UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA

and

ex rel. CHARLES COYLE
2765 Bleiler Hill Road
New Tripoli, PA 18066

Plaintiffs,

Case No. _____

FILED UNDER SEAL

Pursuant to 31 U.S.C. § 3730
(False Claims Act)

v.

PARADIGM SPINE, LLC
505 Park Ave # 14
New York, NY 10022

Serve: Resident Agent
Corporation Service Co.
2711 Centerville Road
Suite #400
Wilmington, DE 19808

MUSCULOSKELETAL CLINICAL
REGULATORY ADVISORS, LLC
1331 H Street, NW 12th floor
Washington, DC 20005

Serve: Resident Agent
National Registered Agents, Inc.
160 Greentree Dr. Ste. #101
Dover, DE 19904

Defendants.

COMPLAINT AND JURY DEMAND

COMES NOW, Plaintiff and *qui tam* Relator Chris Coyle, by and through undersigned counsel, and files this False Claims Act ("FCA") Complaint, on behalf of himself and the United States of America, against Defendants Paradigm Spine, LLC ("Paradigm") and

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Musculoskeletal Clinical Regulatory Advisors, LLC ("MCRA") for damages and civil penalties arising out of the Defendants' violations of the FCA, 31 U.S.C. §§ 3729-3733 *et seq.* and Federal Anti-Kickback Statute and their various state counterparts related to causing improper payments from Medicaid, Medicare, TRICARE, DOD and other federally and state-funded government healthcare programs.

NATURE OF THE CASE

1. This is an action for money damages, including treble damages and civil penalties, on behalf of the United States of America under the FCA, 31 U.S.C. §§ 3729-33, Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-397 ("FDCA"), arising from false and/or fraudulent statements, records, and claims made or caused to be made by the Defendants Paradigm and MCRA and/or its agents and employees, for its intentional, false and misleading off-label marketing campaign, for its intentional, false and misleading marketing campaign to cause false and improper medical coding, for its unlawful and improper anti-kickback scheme and for sustaining a fraudulent course of conduct to obtain improper and unwarranted government reimbursement, all in violation of the FCA.

2. This *qui tam* case is brought against Paradigm and MCRA for causing the submission of false claims for services, for misrepresentations to the Food and Drug Administration ("FDA") and others, and for its false and misleading off-label marketing regarding three spine medical devices in particular, known as: (a) Coflex-F; (b) Coflex; and (c) DSS Stabilization System.

3. According to its Pre-Market Approval ("PMA"), Coflex is an Interlaminar Technology device indicated for use in one- or two-level lumbar stenosis from Ll-L5 in

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skeletally mature patients with at least moderate impairment in function. Coflex is intended to be implanted midline between adjacent lamina of one or two contiguous lumbar motion segments. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s). Coflex is a new, investigational and experimental device whose safety and effectiveness has not been proven.

4. According to its 510k, the Coflex-F Implant System is a posterior, non-pedicle supplemental fixation device intended for use with an interbody cage as an adjunct to fusion at a single level in the lumbar spine (L1-S1). It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease–defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies–with up to Grade I spondylolisthesis. The Coflex-F Implant System is a spinous process fixation device that stabilizes the spinous processes and spine to act as an adjunct to fusion.

5. According to its 510k, DSS Stabilization System–Rigid is intended as a single-level system for noncervical pedicle fixation from the T4 to S I vertebrae in skeletally mature patients to help provide immobilization and stabilization of spinal segments as an adjunct to fusion for a range of conditions. It is to be used with bone graft. The DSS Rigid and the DSS Slotted are expressly banned from being used together in the 510k.

6. Generally, the false and misleading statements and claims made by Paradigm regarding these devices include, but are not limited to, the following:

a.) Off-label promotion and false statements to health care providers and insurers:

i) False and misleading statements and omissions by Paradigm and MCRA in training materials, device training to doctors and promotional materials that for physician billing, the use of CPT code 22840 is proper for Coflex and is reimbursable by Medicare and other government payors;

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ii) False and misleading statements and omissions by Paradigm in training materials, device training to doctors and promotional materials stating that the Coflex-F devices are indicated for more than a single spinal level, when they are not so indicated or approved;

iii) False and misleading statements and omissions by Paradigm in training materials, device training to doctors and promotional materials stating that the DSS Rigid device is indicated for more than a single spinal level and/or in the cervical spine, when it is not so indicated; and

iv) False and misleading statements and omissions by Paradigm in training materials, device training to doctors and promotional materials stating that the DSS Rigid Coupler and Slotted Coupler devices are indicated to be used together, when they are expressly prohibited from such use.

b.) Kickbacks to physicians to induce the use of Coflex implants paid for by federal and state health care programs. Paradigm has violated the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b and similar state statutes, by, *inter alia*, offering and providing illegal remuneration to physicians, in the form of investment opportunities and/or ownership in Paradigm, in addition to cash, travel, lodging, meals and/or entertainment, as an inducement to:

i.) use Coflex, Coflex-F and DSS for both on-label and off-label uses as summarized above and detailed below;

ii.) to bill Coflex under an improper CPT code as summarized above and detailed below; and

iii.) for investor surgeons to use Paradigm devices over competitor devices and despite or regardless of medical judgment.

7. In the course of its campaign to cause health care providers to improperly code Coflex, Defendants Paradigm and MCRA have and continue to knowingly misrepresent the Coflex device as approved for marketing by the Food and Drug Administration ("FDA") as "non-segmental instrumentation" and therefore subsequently reimbursable under Medicare and other government payors, when in fact, Coflex remains investigational and experimental, and not approved for marketing by the FDA as non-segmental instrumentation and does not have its own Category 1 code. By masking Coflex under the guise of CPT 22840, Paradigm has intentionally avoided the review, scrutiny and reimbursement denial that would otherwise

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follow the use of an investigational device like Coflex. It has also avoided the data collection and analysis that is normally done by the FDA and other agencies when investigation devices are used and are coded using a T-code. In summary, through the use of incorrect and misleading billing and description codes to represent Coflex, Defendants fraudulently caused hospitals and physicians to obtain and continue to obtain reimbursement from Medicare, the states and other government payors that should not have been paid.

8. In the course of its off-label marketing scheme, Paradigm has made false and misleading statements to treating doctors, hospitals and others to the effect that Coflex is lawfully and properly coded and billed as CPT 22840 and thereby eligible for Medicare, Medicaid and other federal and state health care program reimbursement when it was not. Also, Paradigm and MCRA have systematically and intentionally omitted from all marketing, promotion and training all of the various guidance regarding Coflex that has advised providers to use 0171T or 22899 (unlisted) for Coflex.

9. Paradigm and MCRA have counseled health care providers to avoid using the trade name "Coflex" in any billing so as to avoid review, and rejection, of claims.

10. In addition, in the course of its off-label marketing scheme, Paradigm has made false and misleading statements to treating doctors, hospitals and others to the effect that the Coflex-F and DSS devices were indicated and approved for the off-label uses being promoted, and therefore eligible for Medicare, Medicaid and other federal and state health care program reimbursement when they are not so approved or indicated.

11. In reliance on Paradigm's false and misleading statements, treating physicians used Coflex-F and DSS devices on their patients in off-label and non-FDA-approved uses. Thus, Paradigm caused physicians to present false claims for payments to Medicare, Medicaid

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and other federal and state health care programs relating to these devices. Paradigm's false statements caused Coflex-F and DSS devices to be unapproved Class II medical devices used in interstate commerce. Additionally, Paradigm's false and misleading statements led to the submission and payment of false claims by Medicare, Medicaid, the VA and other federal health care programs, which violated § 3729(a)(l)(A)–(C) of the FCA. Paradigm intended its off-label promotion to cause the submission of false claims and to result in improper payments by federal and state health care programs.

12. Paradigm's false and misleading statements and omissions respecting Coflex-F and DSS caused others' submissions of false claims for reimbursement to Medicare, Medicaid, VA and other federal and state health benefit programs, claims that would not have been paid if those health benefit programs had been fully informed about the experimental nature of Coflex or the lack of approval for indicated uses promoted by Defendant.

13. Paradigm knew or should have known that its conduct, representations and omissions were contrary to federal and state laws, were without FDA approval, and were off-label, false and misleading.

14. Paradigm's material representations that: (1) Coflex-F is indicated and approved for more than one spinal level; (2) that Coflex-F is indicated and approved for use without an interbody; (3) that DSS is indicated and approved for more than one spinal level; and (4) that the DSS Rigid and Slotted couplers were to be used together, were known or should have been known to be false and caused the submission of false claims by doctors and hospitals who billed federal and state health care programs for these non-approved devices and/or non-approved indications.

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15. As the direct, proximate and foreseeable result of Paradigm's false and fraudulent conduct as set forth herein, it: (a) caused physicians to submit false claims to Medicare, Medicaid and other federal and state health care programs seeking reimbursement for uses of Coflex-F devices that Paradigm knew were not approved by the FDA and were off-label and therefore ineligible for federal and state health care program reimbursement; (b) caused physicians to submit false claims to Medicare, Medicaid and other federal and state health care programs seeking reimbursement for uses of DSS devices that Paradigm knew were not approved by the FDA and were off-label and therefore ineligible for federal and state health care program reimbursement; (c) caused physicians to submit false claims to Medicare, Medicaid and other federal and state health care programs seeking reimbursement for Coflex under billing codes that Paradigm knew or should have known were improper and not recommended or approved; and (d) used false or fraudulent statements to get federal and state health care programs to reimburse millions of dollars in false and fraudulent claims submitted by physicians and hospitals.

16. Paradigm's unlawful scheme to promote the use of Coflex-F and DSS devices for indications that were not FDA approved greatly increased these devices' sales to the great financial benefit of Paradigm, but caused federal and state health care programs to pay millions of dollars for the use of medical devices that were not approved, were not reasonable and medically necessary, were investigational and experimental, and/or were medically unsafe for non-approved uses.

17. As a direct result of Paradigm's and MCRA's improper practices as detailed herein, the Federal Treasury and those of the states named herein have been damaged in a

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substantial amount that is yet to be determined, but currently estimated at approximately $50 million.

PARTIES

18. Plaintiff-Relator C. Christopher Coyle is a resident of New Tripoli, Pennsylvania. Relator has been a medical sales management professional for over 20 years. He has been employed by Paradigm from approximately February 2011 to the present as a Regional Sales Manager for the Northeast. In this capacity, Relator manages regionals sales distribution, sales goals and oversees sales training for distributors in New York, New Jersey, Pennsylvania, Delaware and Maryland.

19. Defendant Paradigm has a principal office at 505 Park Ave. # 14 New York, NY 10022 and was incorporated in Delaware in 2002. Marc R. Viscogliosi is the Chief Executive Officer and is a director. Paradigm is a privately-held medical device company that focuses on design, development, production, sales and distribution of spinal implants, trials, instruments and sterilization. It is funded by private investors (some of whom are physicians), the largest investor being the Viscogliosi Brothers. Paradigms' gross sales for 2012 was $11 million, for 2013 was $28 million and through April 2014, was $9 million.

20. Defendant MCRA was organized under the laws of Delaware and has a principal place of business of 1331 H Street, NW 12th floor, Washington, DC 20005. Marc Viscogliosi is the co-founder of MCRA and MCRA is funded by the Viscogliosi Brothers. At all times herein, Defendant MCRA was an agent of Defendant Paradigm.

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JURISDICTION AND VENUE

21. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732. 31 U.S.C. § 3732 specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

22. This Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. § 3732(a), because it authorizes nationwide service of process and because the Defendant has at least minimum contacts with the United States. Moreover, the Defendant can be found in, transacts - or has transacted - business in Maryland and employed Maryland residents.

FACTS COMMON TO ALL COUNTS

Background

Paradigm

23. Paradigm was formed in 2005 by Marc Viscogliosi and Guntmar Eisen as a spinal implant company.

24. Paradigm markets and sells three spinal devices: (1) DSS Stabilization System ("DSS"); (2) Coflex-F Interlaminar Stabilization System ("Coflex-F"); and (3) Coflex Interlaminar Stabilization ("Coflex").

25. Paradigm has approximately 19 employees and 69 distributors. Its distributors are 1099 contractors who market, promote and sell Paradigm's devices per Paradigm's instructions and for Paradigm's benefit. At all times herein, Paradigm controls the manner in which its distributors market, promote, sell and train physicians on its devices. Moreover, Paradigm jointly engages with its distributors in the education and training of physicians on its devices.

26. Paradigm currently operates in numerous states, including Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Indiana, Maryland, Minnesota, New Jersey,

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Nevada, Pennsylvania, Texas, Washington, Tennessee, Montana, Kentucky, New York, Ohio, South Dakota, Oregon, Missouri, Illinois, West Virginia, Washington, Wyoming, Virginia, Michigan, Massachusetts, Connecticut and Iowa.

27. Paradigm had a total gross revenue in 2013 of $28 million, the vast majority of which is comprised of Coflex (more than $18 million), with the least sales for DSS (approximately $1-2 million).

FDA Regulation of Medical Devices

28. The FDA is an agency of the United States Government responsible for protecting the health and safety of the public by assuring, among other things, that medical devices intended for use in the treatment of humans are safe and effective for their intended uses and that the labeling of such devices bear true and accurate information.

29. Pursuant to its statutory mandate, the FDA regulates the manufacture, labeling, and shipment in interstate commerce of medical devices.

30. Under the Federal Food, Drug and Cosmetic Act (Title 21, United States Code, §§ 301-397, the "FDCA"), and pursuant to Title 21, United States Code § 321(h), the term "device" includes "an . . . implant . . . or other similar or related article . . . which is . . . intended for use in . . . the treatment or prevention of disease of man . . . or intended to affect the structure or any function of the body of man . . . which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

31. The FDA is charged with protecting American consumers by enforcing the FDCA of 1938, the FDA Modernization Act of 1997 and related public health laws. Under the FDCA, the FDA has the responsibility of ensuring that medical devices are safe and effective

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before they can be marketed within the United States. The FDA's authority to regulate medical devices arises in part from the FDCA, as amended by the Medical Devices Act of 1976 ("1976 Amendments"). General statutory standards for determining the safety and effectiveness of devices are set forth in the FDCA, 21 U.S.C. §§ 360c(a)(2) and (a)(3). These standards are implemented by regulations set forth at 21 C.F.R. § 860.7.

32. Under federal law, medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval ("PMA").

33. Under the statute, a Class III device is one that: (1) cannot be classified as a Class I device because insufficient information exists to provide reasonable assurance of its safety and effectiveness; and (2) cannot be classified as a Class II device because insufficient information exists to determine that the special controls would provide reasonable assurance of its safety and effectiveness. 21 U.S.C. § 360c. Class III devices are also so categorized because they "present a potential unreasonable risk of illness or injury" and must be "subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness." *Id.*

34. New Class III devices must receive PMA from the FDA before they can be sold. To obtain PMA, a manufacturer must submit a detailed application that contains "specimens of labeling proposed to be used for such device." *Id.* § 360e(c)(1). The FDA reviews the device's labeling to evaluate the "safety and effectiveness under the conditions of use set forth on the label." *Id.* § 360c(a)(2)(B). It also "must determine that the proposed

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labeling is neither false nor misleading." *Id.* § 360e(d)(1)(A). After this evaluation, the FDA will only grant PMA if it finds there is a "reasonable assurance" of the device's "safety and effectiveness." *Id.* § 360e(d). Once a device has received PMA, the manufacturer cannot make changes to any feature of the device without obtaining FDA permission.

35. To market a Class II device, manufacturers are typically required to submit a 510(k) Premarket Notification to the FDA, unless the device is determined to be exempt from 510(k) requirements.

36. In submitting a 510(k) Notification, the manufacturer must demonstrate that a device is at least as safe and effective (*i.e.* that the device is "substantially equivalent") to a legally marketed device (21 C.F.R. § 807.92(a)(3) ("predicate device")). A legally marketed device, as described in 21 C.F.R. § 807.92(a)(3), is a device that was legally marketed prior to May 28, 1976; a device which has been reclassified from Class III to Class II or I by the FDA; or a device which has already been found substantially equivalent through the 510(k) process.

37. A device is substantially equivalent if, in comparison to a legally marketed device, it: (1) has the same intended use; and (2) has the same technological characteristics as the legally marketed device OR has different technological characteristics and the manufacturer submits information to the FDA which does not raise new questions of safety or effectiveness and/or demonstrates that the device is as safe and effective as the legally marketed device.

38. For Class II medical devices requiring Premarket Notification, the manufacturer may not proceed to market the device in the United States until the manufacturer receives an order from the FDA declaring a device to be "substantially equivalent" to a predicate device.

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39. Premarket Notifications are governed largely by 21 CFR Part 807 Subpart E. A 510(k) must demonstrate that the device is substantially equivalent to one legally, commercially distributed in the United States: (1) before May 28, 1976; or (2) to a device that has been determined by FDA to be substantially equivalent.

40. Under the CFR, a 510(k) is required when:

a.) Introducing a device into commercial distribution (marketing) for the first time after May 28, 1976;

b.) A **different intended use** is proposed for a device which is already in commercial distribution. 21 CFR 807 specifically requires a 510k submission for a major change or modification in intended use. **Intended use is indicated by claims made for a device in labeling or advertising. Most, if not all changes in intended use will require a 510(k)**; or

c.) There is a change or modification of a legally marketed device and that change could significantly affect its safety or effectiveness.

21 CFR § 807.81. (Emphasis supplied). A few Class II devices are expressly exempt from Premarket Notification, none of which apply here.

41. If the FDA makes a finding of "substantial equivalence" based on the manufacturer's Premarket Notification, the device is then "cleared" for marketing and can be marketed only for the intended use stated on the label as cleared by the FDA.

42. If the manufacturer intends to market the device for a new or different intended use from that cleared for the predicate device, a new 510(k) Notification is required to include supporting information to show that the manufacturer has considered what consequences and effects the new use might have on the device's safety and effectiveness.

43. For both Class III and Class II devices, the manufacturer is not permitted to promote its devices for any use other than the intended uses on the label as cleared or approved by the FDA.

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44. For a Class II device, a medical device is "misbranded" if the manufacturer of the device has failed to provide the FDA with Premarket Notification of a new or non-FDA-sanctioned intended use ninety days prior to introducing the device into interstate commerce for such use.

45. The FDCA also contains provisions on misbranding and false or misleading labeling. According to Section 502, a device is misbranded if: its labeling is false or misleading in any way; its label does not bear adequate directions for use, including warnings against use in certain pathological conditions; it is dangerous to health when used in the dosage or manner or with the frequency or duration prescribed, recommended or suggested in the labeling.

46. A device may be deemed "misbranded" if its label, including *all* written, printed, or graphic matter upon any article or any of its containers or wrappers or any other thing accompanying such article, at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce, fails to reveal material facts, the consequences that may result from use, or the existence of a difference of opinion about its appropriate use. *See, e.g.* 21 U.S.C. §§ 331(a) and (b), 352(a), (i) and (n); 21 C.F.R. § 201.57. The term "accompanying" a product, as used in Section 502, has been interpreted by the courts to include posters, tags, pamphlets, circulars, booklets, brochures, instruction books, etc. and "most if not all advertising" about the product.

Hospital Medicare Programs

47. The payment hospitals receive through Medicare for covered services vary depending on the setting (*e.g.,* inpatient or outpatient) where the services were performed. Inpatient services performed by hospitals are generally reimbursed on a "per case" basis.

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Thus, each inpatient hospitalization is assigned a Diagnosis Related Group (DRG) based on the nature and severity of the patient's diagnosis and the services performed. The pre-determined reimbursement rate based on the DRG is then paid by Medicare. The DRG reimbursement rate is paid to the hospital regardless of the duration of patient stay or the number of services provided.

48. A process called "grouping" assigns DRGs. A software program known as a "grouper" reviews various data related to the hospitalization such as the patient's diagnosis and the procedures performed to determine the appropriate DRG for the treatment.

49. In most cases, the services and procedures performed by a hospital serve as the most important data indicator affecting the DRG grouper's decision. These service and procedures are classified and reported using International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9-CM") system, established by CMS and the National Center for Health Statistics. This coding system is also known as the "ICD-9 procedure codes."

50. Items and services in the outpatient setting are also bundled and paid by Medicare so that hospital providers are reimbursed for the procedures performed, including the cost of equipment. Hospitals use Ambulatory Payment Classifications ("APC Codes") to bill for costs associated with outpatient services.

Physician Payments Through Medicare

51. Services that are provided by a physician in the course of inpatient or outpatient hospital services are billed separately. Thus, they are not billed through DRG or APC payment.

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52. Physicians are reimbursed by Medicare and other insurers through billing codes provided under the Healthcare Common Procedure Coding System ("HCPCS") and the Current Procedural Terminology ("CPT"). As with payments made under DRG and APC for hospital services, the purpose of the billing codes is to bundle similar types of procedures that consume similar amounts of resources.

53. A methodology called Resource Based Relative Value Scale ("RBRVS") is used for determining physician payment values for Medicare. Each procedure code is given a point value known as a Relative Value Unit ("RVU") which is then multiplied by a conversion factor set by Congress resulting in a payment rate for each code.

54. The RBRVS system works in conjunction with the HCPCS which is a standardized coding system that is divided into two principal subsystems, referred to as level I and level II of the HCPCS. These are designed to ensure that Medicare and other health insurance programs process claims in an orderly and consistent manner.

55. Current Procedural Terminology ("CPT") constitutes Level I of the HCPCS. The CPT is a numeric coding system that is maintained annually by the American Medical Association ("AMA"). CPTs consist of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. CPT Codes are standardized and used by providers to consistently identify services and procedures for which they bill public and private health insurance programs.

56. CPT Codes are divided into three categories of codes. Category I codes consist of five numbers and are the most prevalent as they represent procedures that are consistent with contemporary medical practice and are widely performed and frequently reimbursable. Category II codes consist of four digits followed by the alpha character "F." These are

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supplemental tracking codes which are used for submitting and evaluating performance measurements.

57. Category III codes are temporary codes used to track new and emerging services, procedures, and technologies. Category III codes allow for data collection and utilization tracking for new procedures or services. Category III codes differ from Category I codes in that they are not performed widely by health care professionals, do not have FDA approval, and the service/procedure has not proven total clinical efficacy. These codes are assigned if there is ongoing or planned research. The codes consist of four digits followed by the letter "T" and sometimes referred to as "T-Codes." Category III codes are temporary and if the procedure or service is not accepted as a Category I code within five years the temporary code will retire (or "sunset") altogether.

58. No RVUs are assigned to these codes and they are often not reimbursable as their safety, efficacy and medical necessity have not yet been proven.

59. If a Category III code is available it must be used instead of any unlisted Category I codes since that is the only way the technology can be effectively tracked and proven safe and effective.

60. According to the AMA's Instructions for Use of the CPT Codebook, providers must "select the name of the procedure or service that accurately identifies the service performed." Furthermore, they must "not select a CPT Code that merely approximates the service provided. If no such procedure or service exists, then [they are to] report the service using the appropriate unlisted procedure or service code."

61. Unlisted codes are Category I codes which are less descriptive than Category III codes and are not tracked. They consist of five digits with the latter two ending in '99.'

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When a procedure or service is given an unlisted code by the service provider they must provide additional information that details the procedure performed so that the carrier may determine whether to reimburse and the appropriate level of reimbursement. The assignment of the code may be correct only after additional documentation is submitted for the service and reviewed by the carrier. On this form, the physician must certify that the services were "medically indicated and necessary to the health of the patient."

Compliance Rules Governing Payments to Hospitals and Physicians

62. No payment will be made under Medicare if the services rendered are not reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A). Services provided by providers to beneficiaries must "be provided economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-(a)(1).

63. In addition, providers seeking reimbursement from Medicare for a medically required service must not make false statements or misrepresentations of material fact concerning requests for payment under Medicare, 42 U.S.C. §§ 1320a-7 and 1320a-7b(a)(1)(2), and 42 C.F.R. § 1001.101(a)(1). If a provider finds or becomes aware of an error or a material omission in claims submitted to Medicare, they must disclose these omissions and/or errors to the Government. 42 U.S.C § 1320-a-7b(a)(3).

False Claims Act

59. The False Claims Act provides, in pertinent part, that any person who:

> "(a)(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

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> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . . or
>
> (a)(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; . . .
>
> is liable to the United States Government for any civil penalty of not less than $5,000 and not more than $10,000, . . . plus 3 times the amount of damages which the Government sustains because of the act of that person."

31 U.S.C. § 3729.

60. For purposes of the False Claims Act,

> the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

Id. § 3729(b) (1986).

61. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the False Claims Act civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

The Medicare Program

62. Medicare is the federal health insurance program that was created in 1965 when Title XVII of the Social Security Act was adopted. 42 U.S.C. §§ 1395, *et seq*. Medicare covers people of age 65 and older regardless of their income or medical history.

63. Medicare is organized into four parts. Part A pays for inpatient hospital stays, skilled nursing facility stays, home health visits (also under Part B), and hospice care. Part B covers physician visits, outpatient services, preventive services, and home health visits. Part C, the Medicare Advantage program, allows beneficiaries to enroll in a private health

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organization, such as a health maintenance organization ("HMO"), and receive all Medicare-covered benefits. Part D is the voluntary, subsidized outpatient prescription drug benefit.

64. The Centers for Medicare and Medicaid Services ("CMS") administers Medicare. However, most of the daily administration and operation of the Medicare program is managed through contracts with private insurance companies that operate as Fiscal Intermediaries. Fiscal Intermediaries accept and pay reimbursement claims under Medicare Part A and some claims under Part B. Acceptance and payment of claims under Medicare Part B are completed through "Medicare Carriers."

65. CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions. 42 C.F.R. § 405.201.

66. Medicare may reimburse for Class II devices if they are approved by the FDA pursuant to the Premarket Notification process.

67. Under Medicare regulations, Medicare will not reimburse providers or institutions or medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not "reasonable" and "necessary" under section I 862(a)(l)(A) of the Act or because it is excluded from coverage for other reasons.

68. Medical devices that are not approved for marketing by the FDA are considered investigational by Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures and services performed using devices that have not been approved for marketing by the FDA.

69. Services that are excluded from coverage include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with

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and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from related noncovered services.

The Anti-Kickback Statute

70. The Anti-Kickback Statute ("AKS") is located in Title XI of the Social Security Act, 42 U.S.C. ch. 7, *et seq.*, which contains Medicare and Medicaid program-related anti-fraud provisions and imposes civil penalties for violations of those provisions. Specifically, the AKS prohibits any person or entity (including physicians or hospitals) from "knowingly and willfully" soliciting, receiving, offering or paying "any remuneration, indirectly, overtly or covertly, in cash or in kind" in return for "referring an individual to a person for the furnishing of any item to or service for which payment may be made in whole or in part under a federal health care program." 42 U.S.C. § 1320a-7b(b)(l)–(2). This includes intent to induce referrals or business orders, including the utilization of medical devices paid as a result of the volume or value of any referrals or business generated. *See* 42 C.F.R. § 1001.952(f).

71. The definition of "federal health care program" for purposes of the AKS includes Medicare, Medicaid and Tricare. This provision makes it unlawful for a physician to make a referral that will lead to a claim being submitted to Medicare for services or products supplied by an entity (such as a medical device company) with which the physician has a financial relationship, unless the relationship is not intended to induce referrals and is exempt under a statutory or regulatory safe harbor.

72. The AKS was passed because of Congressional concerns that payoffs to those who can influence health care decisions will result in goods and services being provided that

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are medically unnecessary, or even harmful, to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult-to-detect harms, Congress enacted a prohibition against the offer or payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality care.

73. The Balanced Budget Act of 1997 amended the AKS to include administrative civil penalties of $50,000 for each act violating the AKS, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. *See* 42 U.S.C. §1320a-7a(a).

74. Such remunerations are kickbacks when paid to induce or reward physicians' utilization of medical devices. Kickbacks increase Government-funded health benefit program expenses by inducing medically unnecessary overutilization of prescription drugs, medical devices and excessive reimbursements. Kickbacks also reduce a patient's healthcare choices, as a physician may use a medical device based on the physician's own financial interests rather than according to the patient's medical needs or safety.

75. The AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protects Paradigm's conduct in this case.

76. The Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, Sec. 6402(g), changed the language of the AKS to provide that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). PPACA also amended

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the AKS's "intent requirement" to make clear that violations of the AKS, like violations of the False Claims Act, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." *See id.* § 1320a-7b(h).

77. As detailed herein, Paradigm's off-label marketing and promotion of the Coflex-F and DSS devices repeatedly violated provisions of the AKS, which in turn resulted in violations of the False Claims Act, because Paradigm's improper kickbacks and incentives induced physicians to choose and utilize Coflex-F and DSS devices for non-approved, non-indicated, off-label uses when they otherwise would not have. Many of those off-label and kickback tainted procedures utilizing Coflex-F and DSS devices were paid for by Medicare, Medicaid and other state and federal government-funded health insurance programs.

78. It is a violation of the False Claims Act to knowingly pay kickbacks to physicians to induce them to utilize a medical device off-label and to seek reimbursement for a medical device from a state or federal government health program or causing others to do so, while certifying compliance with the Medicare Anti-Kickback Statute (or while causing another to so certify) or billing the government as if in compliance with these laws.

Specific Allegations

A. *Paradigm and MCRA's scheme to improperly code and bill for Coflex.*

Guidance to use the T-Code or Unlisted Code

79. Paradigm received its Premarket Approval from the FDA for the Coflex device on or about October 17, 2012.

80. Coflex was deemed a Class III device and given product code NQO. Code NQO denotes a "Prosthesis, Spinous Process Spacer/Plate" which is defined by the FDA as an "interspinous process plate that is implanted between the spinous processes or attached to the

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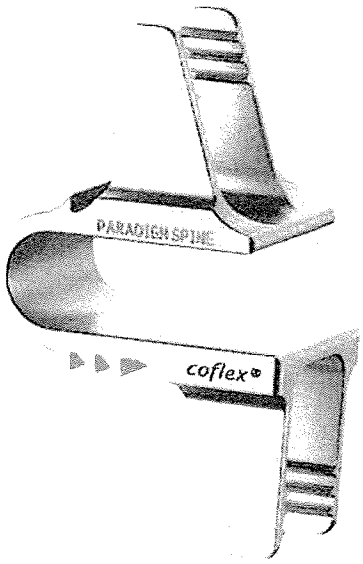
spinous process." *See Product Classification*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=4302 (last visited June 22, 2014.) The device looks like this:



81. According to its PMA, Coflex was "intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments" and "interlaminar stabilization is performed after decompression of stenosis at the affected level(s)."

82. The PMA does not advise on the proper coding or billing pathways for Coflex.

83. Coflex was given an expiration date for the device of five years. Given the new and investigational technology, as part of the Premarket Approval of Coflex, the FDA required Paradigm to submit Annual Reports under 21 CFR 814.84 and also to conduct and submit two Post-Approval Studies "to provide long-term device performance and to evaluate device performance under actual conditions of use." This included an Extended Follow-up of Premarket Cohort study with the primary objective of the study is to evaluate the overall success rate, and a Real Conditions of Use study with a primary objective to "assess the

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treatment group for superiority compared to the control group." Paradigm was to submit various reports to the FDA in conjunction with these studies.

84. Paradigm received significant guidance on the proper coding pathways for Coflex from non-affiliated and non-interested parties, associations and payors. This included at least two CMS administrators, the North American Spine Society, the American Medical Association and numerous state insurance medical policies, as follows, *none of which* advised the use of CPT 22840.

85. In 2012, prior to PMA approval, Cahaba Government Benefit Administrators, the CMS administrator covering the region including Georgia, Alabama and Tennessee, had already issued a Local Coverage Determination noting that 0171T and 0172T (Insertion of posterior spinous process distraction device) was being added to the CMS Medicare Coverage Database (at the time, the trade name used to describe the device was the X-Stop device since Coflex was yet to be approved). As such, upon entering the market, Paradigm knew that at least one CMS administrator was requiring the T-code be used for these devices.

86. Shortly after FDA approval for Coflex, Paradigm received written guidance from the North American Spine Society ("NASS") regarding its opinion on the proper coding for Coflex. At that time, NASS recommended to Paradigm that Coflex be coded using the investigational T-code, 0171T, denoting "Lumbar Spine Process Distraction." NASS did not recommend or advise the use of 22840.

87. Capital Blue, the Federal Employees health care plan, issued policy number MP-1.111 in 2007 and most recently reviewed in November 2013. It concluded that Coflex, described in detailed in the policy, is "investigational," as follows:

> Interspinous Distraction Devices are considered investigational as a treatment of neurogenic intermittent claudication as there is insufficient evidence to support a

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> conclusion concerning the health outcomes or benefits associated with this procedure. Use of an interlaminar stabilization device following decompressive surgery is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.
>
> Dynamic stabilization devices including, but not limited to the Dynesys® Spinal System
> are considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure

Though it does not discuss reimbursement or coding, an investigational device should be billed with the T-code, which signifies experimental or investigation. Moreover, an investigation device for which there is "insufficient evidence to support a conclusion concerning the health outcomes or benefits" is normally not reimbursable.

88. Blue Cross Blue Shield of Kansas (providing the state health plan, Medicare supplemental health coverage and coverage under the Affordable Care Act) issued a medical policy on "Interspinous Distraction Devices (Spacers)" effective 2010 and most recently reviewed March 19, 2013. It references and discusses Coflex in detail. Its stated policy is that, "interspinous distraction devices are considered **experimental/ investigational** as a treatment of neurogenic intermittent claudication." In summary, this medical policy states that, "because the impact of this technology on net health outcome is not known, these devices are considered investigational." This medical policy instructs to use CPT code 0171T with Coflex. It also clarifies that "prior to 2007, the procedure should have been coded using CPT code 22899 (unlisted procedure, spine)." Coflex was not approved at that time. Nowhere does the policy mention using CPT 22840.

89. Blue Cross Blue Shield of Alabama (providing the state health plan, and covering over 90 percent of Federal employees residing in Alabama) issued medical policy #282, last updated August 2013, and specifically addressing Coflex. Its stated policy is:

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> **Interspinous distraction devices do not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational** as a treatment of neurogenic intermittent claudication.
>
> Use of an **interlaminar stabilization device following decompressive surgery does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

(Emphasis in original). This medical policy instructs to bill using the T-code (0171T), or possibly the unlisted code, 22899. Nowhere does the policy mention using CPT 22840.

90. Blue Cross Blue Shield of Arizona (providing the state health plan, Medicare Part D, Medicare Advantage, Medicare Supplement members and also covering those receiving healthcare under the Affordable Care Act) issued its Medial Coverage Guideline regarding Interspinous Distraction Devices (Spacers), last review date January 2013, which specifically references Coflex. Its policy is:

> Interspinous process decompression is considered *experimental or investigational* based upon:
> 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
> 2. Insufficient evidence to support improvement of the net health outcome.

(Emphasis in original). No bill codes are discussed in this Guideline.

91. Blue Cross Blue Shield of Idaho (providing the state health plan, covering medigap, Medicare Advantage and other Medicare and Medicaid supplemental health care plans, as well as those receiving healthcare under the Affordable Care Act) issued its Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers) medical policy # MP 7.01.107, last reviewed May 2013. It specifically references Coflex. Its policy is:

> Interspinous distraction devices are considered investigational as a treatment of neurogenic intermittent claudication
> Use of an interlaminar stabilization device following decompressive surgery is considered investigational

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92. The Idaho medical policy also specifically instructs the exclusive use of the T-code for Coflex and does not mention the use of CPT 22840 anywhere:

> Effective January 1, 2007, there are specific CPT category ill codes fur this procedure:
>
> 0171 T Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament fur insertion, and imaging guidance), lumbar; single level
> 0172T each additional level
> Effective January 1, 2007, there is also a HCPCS "C" Medicare pass-through code for the device:
> C 1821 Interspinous process distraction device (implantable)
> Prior to 2007, the procedure should have been coded using CPT code 22899 (unlisted procedure, spine).

93. Blue Cross Blue Shield of Massachusetts (providing the state health plan, plus Medicare Advantage, Medicare Supplement, plans for federal and postal employees, as well as for those receiving healthcare under the Affordable Care Act), issued its Interspinous and Interlaminar Stabilization-Distraction Devices Spacers medical policy # 584 stating as follows:

> Interspinous distraction devices are **INVESTIGATIONAL** as a treatment of neurogenic intermittent claudication.
>
> Use of an interlaminar stabilization device following decompressive surgery is **INVESTIGATIONAL.**

(Emphasis in original.) The policy references using CPT code (0171T) or HCPCS code C1821. It does not suggest using CPT 22840.

94. Blue Cross Blue Shield of Michigan (providing the state health plan , plus Medicare Advantage, supplemental Medicare and Medicaid beneficiaries) issued a medical policy titled "Interspinous/Interlaminar Distraction Devices (Spacers)" last effective date May 2013. This medical policy specifically refers to Coflex. This medical policy concludes:

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> Interspinous/interlaminar distraction devices are considered experimental/investigational as a treatment of neurogenic intermittent claudication and/or spinal stenosis resulting in leg/buttock/groin pain, with or without back pain. These devices have not been scientifically demonstrated to result in long-term improved patient clinical outcomes.

This policy also expressly instructs the use of the T-code for these devices:

> Claims for the implantation of these systems should use the CPT codes 0171T Insertion of posterior spinous process distraction device, lumbar; single level and 0172T Insertion of posterior spinous process distraction device, lumbar; each additional level.

This policy does not mention the use of CPT 22840 for these devices.

95. Blue Cross Blue Shield of Montana (providing the state health plan, plus Medicare Advantage, Medicare Part D, Medicare supplements and coverage for those getting insurance under the Affordable Care Act) issued a medical policy regarding Interspinous Distraction (Spacers) and Interlaminar Stabilization Devices, last revised July 2013. This policy expressly references Coflex and concludes:

> **Investigational**
> Blue Cross Blue Shield of Montana (BCBSMT) considers interspinous distraction devices (spacers) **experimental, investigational and unproven** for all indications. Use of an interlaminar stabilization device following decompressive surgery is considered **experimental, investigational and unproven**.

(Emphasis in original). Regarding coding, this medical policy states, that these devices are "experimental, investigational and unproven for all codes."

96. Blue Cross Blue Shield of North Carolina (providing the state health plan, plus Medicare Part D, Medicare Advantage and supplemental Medicare) issued a Corporate Medical Policy on Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers), last revised August 2013. The policy expressly references Coflex, and flatly denies coverage:

> Interspinous distraction devices and interlaminar stabilization devices are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

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97. Blue Cross Blue Shield of Tennessee issued a medical policy regarding Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers); Interspinous Fixation (Fusion) Devices originally effective June 2013, concluding as follows:

> Use of interspinous stabilization/distraction devices (spacers) for all indications, including, but not limited to, use as a treatment for neurogenic intermittent claudication is considered ***investigational.***
>
> Use of interlaminar stabilization/distraction devices (spacers) for all indications, including, but not limited to, use following decompressive surgery is considered ***investigational.***
>
> Use of interspinous fixation (fusion) devices for all indications, including, but not limited to, use in combination with interbody fusion or alone for decompression in individuals with spinal stenosis, is considered ***investigational.***

(Emphasis in original). Coding is not discussed in this policy, but use of the T-code can be presumed since the T-code is the CPT denoting "investigational" devices.

98. Blue Cross Blue Shield of Florida (including Medicare Advantage, Medicare Part D, Medicare supplement and those insured under the Affordable Care Act) issued a Medical Coverage Guideline regarding Subject: Interspinous and Interlaminar Stabilization/Distraction (Spacers) and Fixation (Fusion) Devices, last revised November 2013. Its position statement reads as follows:

> **Interspinous and interlaminar distraction, stabilization and fixation devices** are considered **experimental or investigational** as a treatment for spinal stenosis, neurogenic intermittent claudication, or any other indication. There is insufficient clinical evidence in the peer reviewed literature demonstrating the safety, efficacy and effects of this technology on long-term health outcomes.

(Emphasis in original). It mentions using CPT 0171T. It does not refer at all to using CPT 22840.

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99. Blue Cross Blue Shield of Mississippi (including coverage for Medicare supplement, disabled residents eligible for Medicare Part B) issued a medical policy on Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers), last updated October 2013. It concluded that:

> Interspinous distraction devices are considered **investigational** as a treatment of neurogenic intermittent claudication.
>
> Use of an interlaminar stabilization device following decompressive surgery is considered **investigational.**

(Emphasis in original). It does not mention CTP 22840, but does list the "investigational code" 0171T for these devices.

100. Excellus Blue Cross Blue Shield (covering 31 counties in central New York and including Medicare HMO and PPO plans as well as those getting insurance under the Affordable Care Act) issued medical policy # 7.01.75, last revised September 2013. It specifically references Coflex by name and concludes as follows:

> Based upon our criteria and assessment of peer-reviewed literature, interlaminar stabilization devices (e.g., Coflex implant) following decompression surgery have not been proven to be medically proven effective and are considered investigational.

This policy does not mention CPT 22840 anywhere, but does reference the use of the "Experimental/Investigational" CPT 0171T.

101. Wellmark Blue Cross Blue Shield (covering Iowa and South Dakota and including Medicare Part D and Medicare supplement plans) issued medical policy #07.01.35, last reviewed April 2014, regarding Interspinous Distraction Devices. It concludes:

> Interspinous distraction devices are considered **investigational.**
>
> There is insufficient evidence in the peer-reviewed medical literature to demonstrate the long-term safety and efficacy of interspinous distraction devices and the durability of the devices. The impact of this technology on net

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> health outcome is not known. There is a need for longer-term outcome data on symptom relief, the need for repeat procedures, and implant survival.

(Emphasis in original). It does not reference 22840. It only references 0171T and HCPS C1821.

102. Anthem (which covers certain areas of Colorado, Nevada, Connecticut, Georgia, Kentucky, Maine, Missouri, New Hampshire, Ohio, Virginia and Wisconsin and includes Medicare plans and federal employee plans) issued medical policy# SURG.00092, last review date November, 2013. This policy specifically discusses Coflex and its position statement is that "implanted devices for treatment of spinal stenosis are considered **investigational and not medically necessary."** (Emphasis in original). The policy references using CPT 0171T and HCPS C1821 "when services are Investigational and Not Medically Necessary." It does not reference CPT 22840.

103. Blue Cross Blue Shield – Regence (covering Oregon, Utah, Idaho and select counties in Washington state) issued a medical policy regarding Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers), policy #155, last reviewed June 2013, expressly referencing Coflex, and concluding:

> Interspinous process and interlaminar distraction/stabilization devices are considered **investigational** for all indications.

(Emphasis in original). This medical policy does not mention the use of CPT 22840. Instead, it refers to CPT 0171T and HCPCS C1821 for these devices.

104. First Coast Service Options. Inc., the CMS contractor with primary jurisdiction over Florida and oversight over Region IV, issued a Local Coverage Determination (LCD) for services performed after February 16, 2009 (revised October 2010). The LDD number is L28775 and is regarding Interspinous Process Decompression ("IPD"). The LCD calls IPD an

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"emerging technology" and places limitations on medical necessity, including that IPD "will NOT be considered medically reasonable and necessary with ANY" of the listed conditions, including degenerative spondylolisthesis greater than grade 1.0, significant scoliosis, cauda equine syndrome, severe osteoporosis and BMI great than 40kg/m^2. The LCD instructs to use CPT code 0171T and HCPCS Code C1821. It continues to caution that "services performed on patients who have received another spinal procedure such as any spinal instrumentation (CPT codes 22840-22849) and laminectomy or laminotomy (CPT codes 63001-63048) may be subject to denial."

105. In April 2013, Paradigm received written notification from Novitas Solutions, Inc. regarding Coflex. Novitas has the Medicare Administrative Contract (MAC) Jurisdiction L (JL), which spans Pennsylvania, New Jersey, Maryland, Delaware and Washington D.C. and the Medicare Administrative Contract (MAC) Jurisdiction H (JH), which spans Colorado, Oklahoma, New Mexico, Texas, Arkansas, Louisiana, Mississippi, Indian Health Service (IHS) and Veterans Affairs (VA). Novitas wrote, "at this time Novitas Solutions is not recognizing the FDA approved system as a service we will pay for." Paradigm did nothing to inform its distributors or physicians of this refusal by Novitas to pay for Coflex. Instead, it continues to advise providers to avoid trade names that might trigger scrutiny and claim rejection.

106. In response to an electronic inquiry to the CPT advisory to the AMA, Paradigm also received written guidance on December 5, 2013 to use the T-code:

> CoFlex is an interlaminar device which still allows motion, **CPT code 0171T, Insertion of posterior spinous process distraction device** (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level, **is appropriate to report when this device is implanted.**

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(Emphasis in original).

107. In order to forge the path for its own proper coding pathway, Paradigm submitted the Coflex device to the AMA's Editorial Panel in the spring of 2013 for its review and consideration of a proper Category 1 CPT code. However, after the unfavorable guidance above, Paradigm decided to withdraw Coflex from AMA consideration on or about February 2014. Paradigm and MCRA insist that Coflex is unique and unlike any other device, particularly including the X-Stop, which has, itself, faced coding and reimbursement challenges.

108. However, concerned with not drawing too much attention to the fact that Coflex has *not* had a Category 1 code for the past 18 months, Paradigm has withdrawn its year-long bid for Coflex to have its own Category 1 code rather than to draw attention to its lack of a viable coding pathway. As such, Coflex is not even under consideration for a Category 1 code.

109. On or about December 4, 2013, NASS sent a second letter to Tim Hunter at MCRA regarding its opinion on the proper coding of Coflex. Approximately one year after it initially advised Paradigm and MCRA to use the CPT T-code for Coflex, NASS changed its opinion in the December 4th letter to suggest using the unlisted code 22899 for Coflex instead. However, it did *not* change its opinion regarding the improper use of 22840, stating in part, "we also do not believe that code 22840 is appropriate as it is an add-on code that must be reported with a fusion."

110. Shortly after receiving the December 4th NASS advisory letter, the Paradigm spine team held an internal conference call to discuss the letter and their next steps. There was open discussion among the Paradigm leadership, its employees and MCRA on how to advise

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physicians how to "cross walk" from an unlisted code to 22840 so that in the end 22840 would still be the code used and reimbursement would be secured. Tim Hunter from MCRA stepped in as the conversation was concluding and said that MCRA would have to consult with "Bright-Bar" (Viscogliosi Brothers' attorneys) on this issue, after which point there was no further discussion of the issue and no resolution.

111. In the end, no advisory went out to the distributors or to the physicians regarding the NASS letter or its confirmed opinion that 22840 is not the proper code for Coflex. Paradigm's distributors and Coflex physicians have not been shown the NASS letter.

Paradigm and MCRA disguise Coflex as properly billed as a Category 1 code

112. Defendant was wildly successful in marketing and promoting Coflex so as to cause physicians and hospitals to bill incorrectly for procedures and to unlawfully obtain government funds. It was only through this false marketing and promotion that Paradigm realized Coflex sales of over $18 million in 2013 for a device with no defined coding pathway.

113. Paradigm intentionally hid and omitted all of the above medical policies, recommendations and determinations, including the NASS T-code recommendation, the Novitas and Cahaba coverage determinations and the AMA advisory instruction from its marketing, promotional and training materials.

114. In the months leading up to (and prior to) FDA approval, Paradigm designed and created a full marketing campaign that was intentionally aimed at causing physicians and hospitals to improperly bill and code Coflex so that providers would be more likely to receive

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payment from insurers, including government payors, and in turn, so that providers would continue to use Coflex to Paradigm's great financial benefit.

115. An integral part of this marketing campaign is Paradigm's partnership with Defendant MCRA. MCRA purports to be an independent advisory firm specializing in clinical, reimbursement, regulatory and compliance in the neuro-musculoskeletal industry.

116. In fact, MCRA is not wholly independent of Paradigm. Not only was MCRA paid to give Paradigm advice and strategies that were specifically requested by Paradigm, but more importantly MCRA is inherently conflicted. MCRA was co-founded by Paradigm's Marc Viscogliosi. Moreover, Paradigm's Executive Vice President, a Director and CMO, Hallett Mathews, MD, is also the former president of MCRA. Moreover, MCRA is funded by the same core investor group that owns Paradigm, the VB brothers. The companies are in fact very closely affiliated and share core ownership. Having the same ownership group creates an inherent conflict of interest, one that was not disclosed by Paradigm or MCRA, and one that tainted MCRA's judgment, advice and opinions as to Paradigm.

117. Working in conjunction with its affiliate and agent, MCRA, Paradigm created a plan to promote the reimbursable Category 1 billing code, 22840, for Coflex despite the fact that Coflex is new, experimental and investigational. Paradigm paid MCRA specifically to formulate a billing and coding strategy for Coflex using reimbursable Category 1 bill code 22840.

118. In a presentation given by MCRA employees Tim Hunter and Tina Murphy to Paradigm employees and distributors on or about September 18, 2012, MCRA noted at the outset that the current coding pathways were not "positive" for Coflex and would lead to an "unfavorable coverage environment." In other words, if Paradigm promoted the proper,

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current, available coding pathways, Coflex would likely not be reimbursed by the majority of payors. Therefore, it recommended "flying under the radar" to get around these coding challenges.

119. MCRA described the Coflex coding pathways as follows:

IDEAL SCENARIO

Physician Code (CPT)	Hospital Code (ICD-9-CM)	Describes	MS-DRG	REIMBURSEMENT
22840	84.59	"other spinal device"	490	**$10,000**

ELEPHANTS in the ROOM

"Flying under the radar" via CPT 22840 WILL NOT guarantee coverage

22840	81.xx	"no device code"	491	**$5,500**
0171T	84.80	"interspinous distraction device"	490	**$0.00 "investigational"**

BACKUP

This option requires a "case by case" review with Detailed "Special Report"
ALLOWS FOR DISTIGUISHING the coflex ® procedure every time
IDEAL coding option above can be used for REIMBURSEMENT "crosswalk"

22899	84.59	"other spinal device"	490	**$10,000 ?????**

120. MCRA admitted that using bill code 22840 would be "flying under the radar," or, in other words, using 22840 would not be correctly and accurately describing the device.

121. From the beginning, MCRA and Paradigm promoted bill code 22840 as the "ideal" coding scenario, which would result in a $10,000 reimbursement for DRG 490 and a $5,000 for DRG 491. They noted that using the T-code, 0171T, would lead to $0.00 reimbursement due to being "investigational." They also noted that as a backup scenario, the unlisted bill code, 22899, could be used and might lead to reimbursement, especially if "cross-walked" back to the "ideal" 22840 coding option.

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122. While the T-code was undesirable because it led to no physician payment, the 22899 unlisted code was also undesirable. Paradigm employees and distributors know, as do the physicians and third party payors, that when bill code 22899 is used, it automatically triggers an audit and review by either the insurer. This necessarily slows down and jeopardizes the reimbursement process to the provider.

123. Paradigm's affiliate and agent, MCRA, described in this pre-PMA training that ideally they could get physicians to bill Coflex using CPT code 22840 for a total physician reimbursement of $1,748 in 2012 from Medicare, and to have hospitals bill MS-DRG 490 for a total hospital reimbursement rate in 2012 of $10,128 from Medicare.

124. In the early spring of 2013, shortly after PMA approval, MCRA issued a Reimbursement Overview Guide, which was distributed by Paradigm to its employees and distributors for mass distribution to all physicians and hospitals. In that reimbursement guide, MCRA stated that 22840 is the proper billing code:

> For physician billing, the use of CPT code 22840 is an established code for non-segmental instrumentation and has an RVU assignment for reimbursement by Medicare and many commercial insurance carriers. Use of this permanent CPT code for description of the implantation of the coflex device is appropriate at this time, in terms of current coding convention and definitions issued by authoritative bodies.

This guide also emphasized that using CPT code 22840 would lead to a Medicare national average payment of $765.86, while using CPT code 22899 would lead to a $0.00 Medicare national average payment.

125. This Guide also actively discouraged providers from using the device name or trade name so as to not raise any red flags, and to more easily facilitate reimbursement:

> Insurers may not ask what brand (e.g., "Coflex") or type of instrumentation will be used in a spine procedure. In communicating with the insurer, the review nurse will typically only inquire the billing code for decompression (CPT 630xx) and the posterior

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instrumentation (CPT 22840).
If asked how the procedure will be coded, it might be helpful to indicate that *instrumentation will be used in accordance with the device's FDA approval.* The pre-authorization nurse may not need to know specific terms. "Spinal stenosis observed" may be enough to relay to the insurer for purposes of pre authorization.

126. MCRA explicitly instructed billing Coflex using CPT 22840. CPT code 22840 has historically been used for hardware or instrumentation. It is defined as "Posterior non-segmental instrumentation (*e.g.*, Harrington rod technique, pedicle fixation across one interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation)." The MCRA Reimbursement Overview expressly instructs providers to use the following description for Coflex to ensure reimbursement, "POSTERIOR NON-SEGMENTAL INTERLAMNINAR STABILIZATION DEVICE."

127. MCRA explicitly instructed omitting any reference to the T-code. CPT code 0171T denotes "Lumbar Spine Process Distraction." The MCRA Reimbursement Overview expressly instructs providers to "AVOID REFERENCE TO "INTERSPINOUS PROCESS" DISTRACTION" when seeking reimbursement for Coflex.

Coding training and promotion

128. In November 2012, as soon as Coflex had received its PMA approval, Paradigm began a full marketing and promotion campaign which always included advising the use of the Category 1 CPT code 22840.

129. This campaign included surgeon training, presentations at the NASS conference and a year-long traveling training and presentation show by CMO, Director and Paradigm investor, Dr. Hallett Mathews. At each of these presentations in late 2012 and throughout 2013, Paradigm instructed the physicians to code using 22840. His statement about 22840 was repeated at the following surgeon trainings:

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2012	
Dallas, Texas	November 16
Dallas, Texas	November 17
Los Angeles, California	December 8
San Diego, California	December 9
2013	
Orlando, Florida	January 19
Phoenix, Arizona	January 26
Philadelphia, Pennsylvania	January 26
Miami, Florida	February 9
Atlanta, Georgia	February 23
New York City	March1
Baltimore, Maryland	March2
Denver, Colorado	March23
Cleveland, Ohio	April 5
Pittsburgh, Pennsylvania	April 6
Washington, DC	April 20

130. For example, at the NASS conference in Dallas, Texas in 2012, in addition to its CMO, Dr. Mathews, Paradigm paid the following physicians to present Coflex for it at this first NASS conference on October 24 and 25, 2012: Dr. Davis, Dr. Peloza and Dr. Pettine. (Drs. Davis and Pettine are also Paradigm physician investors). When Dr. Mathews presented to the physicians at NASS, he represented that because Coflex is interlaminar, "it is 22840."

131. As another example, on Monday, November 12, 2012, Paradigm held a private dining event for interested physicians at the River Palm Terrace in Fairlawn, NJ. Paradigm's Dr. Mathews led the discussion of Coflex at this physician dinner and advised to code using CPT 22840. There was no discussion to use the T-code or the unlisted code. There was no discussion that the device was investigational and experimental and would not be reimbursed by many payors, including certain federal and state insurers.

132. In January, 2013, Relator received a coding question from Geisinger Health System in Pennsylvania about Coflex. He directed Geisinger to MCRA to answer Geisinger's coding inquiry. On or about that time, MCRA's Senior Manager for Coding & Coverage

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Access emailed Geisinger advising the use of 22840 and DRG 490 for Coflex as follows:

> Good Morning. Paradigm Spine has engaged MCRA, coding and reimbursement consultants to support coding and reimbursement for their co flex interlan1iniar stabilization device.
> Chris Coyle, on behalf of Dr. Schlifka, has asked that I reach out to you regarding facility coding for the coflex procedure he is performing on DOS 1-25-13.
> In brief, the procedure involves a lumbar decompression (CPT 63030 or 63047) at one or two levels as well as the application of a posterior, non-segmental instrumentation for stabilization (**CPT 22840**).
> The [*sic*] is a newly FDA approved device, unlike another, and does not involve a fusion or graft procedure. This being new may raise coding confusions which we have provided explanation of in the attached documents.
> Facility ICD-9 procedure coding should include both 03.09 and 84.59 to accurately capture the device and map to **MS-DRG 490**.
> Attached are physician coding solutions, facility coding solutions and the MCRA reimbursement Overview of the coflex procedure.
> Please feel free to ask us any questions that you have after reviewing the attached.
> We can be reached at:
> Reimbursement Management Center
> 888-796-8411

(Emphasis supplied).

133. Dr. Schlifka did perform a surgery on D.O.S. on January 25, 2013 and another surgery on March 4, 2013 at Geisinger hospital. For these surgeries, both he and the hospital coded for Coflex as advised by MCRA. Another Geisinger surgeon, Dr. Cantando, performed surgery on Medicare patient J.H. in Wilkes Barre, Pennsylvania on January 3, 2014. He used one size 16 Coflex device at a cost of $5,500 at level L4-L5 and per MCRA's instruction, billed 22840 and was paid.

134. Throughout late 2012 and all of 2013, Paradigm trained its distributors and trained physicians to use the Category 1 code for Coflex. It always pushed 22840, rarely

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offered 22899 as an alternative, but it never discussed using the T-code. They always encouraged the use of DRG 490 for hospitals, which yields the higher reimbursement than the out-patient code (491). The following is a typical slide contained in a Paradigm training presentation given to distributors about Coflex and meant for distributors to share with physicians:

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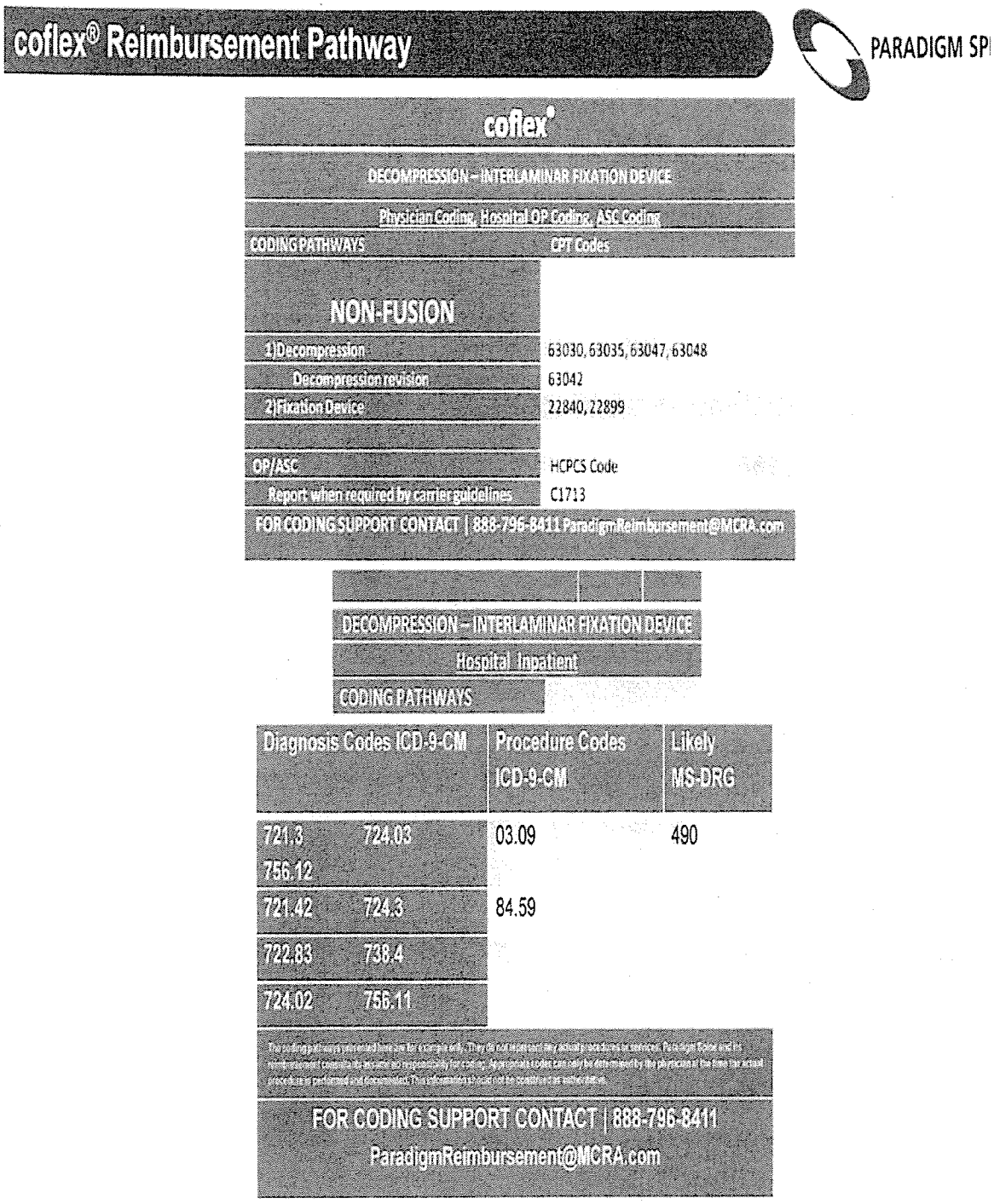

coflex® Reimbursement Pathway

PARADIGM SPI

coflex®

DECOMPRESSION – INTERLAMINAR FIXATION DEVICE

Physician Coding, Hospital OP Coding, ASC Coding

CODING PATHWAYS	CPT Codes
NON-FUSION	
1)Decompression	63030, 63035, 63047, 63048
Decompression revision	63042
2)Fixation Device	22840, 22899
OP/ASC	HCPCS Code
Report when required by carrier guidelines	C1713

FOR CODING SUPPORT CONTACT | 888-796-8411 ParadigmReimbursement@MCRA.com

DECOMPRESSION – INTERLAMINAR FIXATION DEVICE

Hospital Inpatient

CODING PATHWAYS	Diagnosis Codes ICD-9-CM	Procedure Codes ICD-9-CM	Likely MS-DRG
	721.3 724.03 756.12	03.09	490
	721.42 724.3	84.59	
	722.83 738.4		
	724.02 756.11		

The coding pathways presented here are for coding only. They do not indicate any actually reimbursed services. Paradigm Spine and its employees assume no responsibility for correct coding and reimbursement which can only be determined by the physician who has the actual procedure performed and documented. This information is not to substitute for individual

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ParadigmReimbursement@MCRA.com

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135. Paradigm sent distributors, physicians and anyone with questions about Coflex coding directly and solely to its paid, biased, and conflicted affiliate, MCRA. The email address and 1-800 phone number on all of these Coflex trainings and marketing materials are exclusively for MCRA, Paradigm's affiliate who authored the 22840 coding scheme for Coflex.

136. In 2014, Paradigm launched the Coflex I MCRA Coding & Reimbursement Webinar Series. This is a weekly WebEx-based conference call hosted by MCRA, LLC and advising on how to code and get reimbursed for Coflex. As of the date of this filing, the message from these weekly coding trainings is still to code using CPT 22840.

137. In addition to marketing Coflex to be billed as 22840, Paradigm and MCRA markete "Upgraded coding for hospital (increased reimbursement)" for Coflex. Specifically, Paradigm and M advise hospitals to bill the, normally outpatient, Coflex procedure as an in-patient procedure using D (Back and Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator) so that it gets covered by Medicare and so the hospital gets reimbursement at a higher rate. The difference for the hospital between billing Coflex as out-patient and in-patient is great. According to MCRA and Paradigm hospital pricing guide, out-patient may not be covered at all, or may be reimbursed at $2,306.77, while coding at DRG 490 as an in-patient procedure yielded $10,482.57 in 2013.

Physicians trained by Paradigm and MCRA code CPT 22840 for Coflex

138. Dr. Loguidice was among the early group of physicians trained in November 2012 by Paradigm's Dr. Mathews. He attended the November 12, 2012 River Palm Terrace dinner presentation in which Dr. Mathews trained and advised the used of bill code 22840 for Coflex. He became a Coflex user. On February 10, 2013, at Warren Hospital, Dr. Loguidice

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operated on 66-year-old, Medicare beneficiary and female patient M.C.F. He used two Coflex devices (a 12mm and a 14mm) on M.C.F. and billed CPT 22840 for the devices and was paid.

139. Two weeks later, on February 27, 2013 at Easton Hospital in Pennsylvania, Dr. Loguidice operated on female Medicare patient S.C. (dob: 12/25/37). He used the 10mm Coflex device at level L3-L4. Paradigm charged $6,250. As trained and instructed by Paradigm, he billed CPT 22840 for this device and was paid.

140. On June 19, 2013 at Easton Hospital in Pennsylvania, Dr. Loguidice operated on female Medicare patient R.G. (dob: 5/6/45). He used two Coflex devices (10mm and 12mm) at levels L3-L4 and L4-L5. Paradigm charged $12,500. On June 9, 2014 at Easton Hospital in Pennsylvania, Dr. Loguidice operated on male Medicare patient J.T.F. (dob: 5/22/34). He used one size 10 Coflex device at level L4-L5. As trained and instructed by Paradigm, he billed CPT 22840 for these devices and was paid.

141. Dr. Dannis was also among the early group of physicians trained in November 2012 by Dr. Mathews. He attended the November 12, 2012 River Palm Terrace dinner presentation in which Dr. Mathews trained and advised the used of bill code 22840 for Coflex. He became a Coflex user. On February 10, 2014, at Clara Maas Hospital in New Jersey, Dr. Dannis operated on a 70-year-old male Medicare patient, R.A.L. (dob: 7/26/43). He used Coflex on the L3-L4 level. As trained and instructed by Paradigm, he billed CPT 22840 for this device and was paid.

142. Dr. Koziol was also among the early group of physicians trained in November 2012 by Dr. Mathews. He attended the November 12, 2012 River Palm Terrace dinner presentation in which Dr. Mathews trained and advised the used of bill code 22840 for Coflex. He became a Coflex user. On January 10, 2013 at St. Barnabas hospital in New

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Jersey, Dr. Koziol operated on male Medicare patient D.F.G. (dob: 10/14/30). He used one 14mm Coflex device. Paradigm charged $6,500. As trained and instructed by Paradigm, he billed CPT 22840 for this device and was paid.

143. Additionally, on June 6, 2013 at St. Barnabas hospital in New Jersey, Dr. Koziol operated on female Medicare patient A.A.D (dob: 11/26/37). He used two 12mm Coflex devices at levels L3-L4 and L4-L5. Paradigm charged $13,000. As trained and instructed by Paradigm, he billed CPT 22840 for these devices and was paid.

144. Further, on June 28, 2013 at St. Barnabas hospital in New Jersey, Dr. Koziol operated on female Medicare patient M.V.F. (dob: 10/20/47). He used one 14mm Coflex device on level L4-L5. Paradigm charged $6,500. As trained and instructed by Paradigm, he billed CPT 22840 for this device and was paid. Since these early surgeries, Dr. Koziol has ceased using Coflex due to his disagreement with the use of 22840 to code the device.

145. Dr. Mark Li attended and completed a Paradigm Spine Coflex training in Pennsylvania on Wednesday, January 2-3, 2013. This training was taught by Paradigm's Hallett H. Mathews, MD, MBA. Dr. Mathews educated and trained the surgeons at this training, including Dr. Li, to code for Coflex using CPT code 22840.

146. On May 30, 2013 at Lehigh Valley hospital in Pennsylvania, Dr. Li operated on male Medicare patient R.S. (dob: 5/16/32). He used one 14mm Coflex device on level L4-L5. As trained and instructed by Paradigm, he billed CPT 22840 for this device and was reimbursed.

147. On June 11, 2013 at Lehigh Valley hospital in Pennsylvania, Dr. Li operated on male Medicare patient R.Z. (dob: 4/16/42). He used one 16mm Coflex device on level L2-

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L3. Paradigm charged $5,850. As trained and instructed by Paradigm, he billed CPT 22840 for this device and was paid.

148. After receiving Paradigm Coflex training (from Dr. Mathews) and being educated to bill it as CPT 22840, on March 5, 2013 at Moses Taylor hospital in Scranton, Pennsylvania, Dr. Henderson operated on female Medicare patient A.M.B. (dob: 7/26/38). He used one size 12 Coflex device at level L4-L5. Paradigm charged $6,500. As trained and instructed by Paradigm, he billed CPT 22840 for this device and was paid.

149. After receiving Paradigm Coflex training (from Dr. Mathews) and being educated to bill it as CPT 22840, on May 20, 2013 at Wilkes Barre hospital in Pennsylvania, Dr. Deluna operated on 83-year-old male Medicare patient E.W. (dob: 10/19/29). He used one size 10 Coflex device at level L4-L5. Paradigm charged $6,500. As trained and instructed by Paradigm, he billed CPT 22840 for this device and was paid.

150. After receiving Paradigm Coflex training (from Dr. Mathews) and being educated to bill it as CPT 22840, on December 12, 2013 at Somerset Medical Center in Somerset, New Jersey, Dr. More operated on 76-year-old female Medicare patient M.S. (dob: 1/27/37). He used one size 14 Coflex device at level L4-L5. Paradigm charged $6,500. As trained and instructed by Paradigm, he billed CPT 22840 for this device and was paid.

151. After receiving Paradigm Coflex training (from Paradigm investor Dr. Mussachio) and being educated to bill it as CPT 22840, on August 8, 2013 at St. Clair Hospital in Pittsburgh, Pennsylvania, Dr. Whiting operated on 78-year-old female Medicare patient B.K. (dob: 1/27/35). He used one size 12 Coflex device at level L4-L5. Paradigm charged $5,750. As trained and instructed by Paradigm, he billed CPT 22840 for this device

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and was paid. After approximately two Coflex surgeries, Dr. Whiting has since stopped using Coflex due to his disagreement with the use of 22840 to code the device.

152. Under the scheme detailed herein, in 2012, 2013 and continuing in 2014, Defendants Paradigm and MCRA deliberately instructed and advised hospitals and physicians, through the off-label promotion of Coflex, to submit claims for Coflex under false billing codes, to omit reference to the T-code and omit reference to the names "Paradigm" or "Coflex" (which might raise red flags for reimbursement), all done in order to obtain improper and undue reimbursement from federal and state insurers. As a result, Medicare, Medicaid and the VA were defrauded and paid providers for services that would not have been reimbursed if they had been coded correctly.

153. The coding practice by these providers demonstrate Defendants' successful attempt to circumvent the T-code and Coflex's status as an experimental and investigational device. It also demonstrates that Defendants were, for the most part, successful in causing physicians and hospitals to defraud Medicare and other health insurance plans to reimburse for procedures and/or devices that are not properly reimbursable.

154. The use of and training on CPT 22840 for Coflex and Defendants' off-label coding and reimbursement scheme continues to this day.

155. A provider seeking reimbursement from Medicare for a medically required service must meet certain obligations. These obligations include the duty to:

a. bill Medicare for only reasonable and necessary medical services, 42 U.S.C. § 1395y(a)(1)(A);

b. not make false statements or misrepresentations of material fact concerning requests for payment under Medicare, 42 U.S.C. § 1320a-7b(a)(1)(2), § 1320a-7, and 42 C.F.R. § 1001.101(a)(1);

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c. provide evidence that the service given is medically necessary, 42 U.S.C. § 1320c-S (a)(3);

d. assure that such services are not substantially in excess of the needs of such patients, 42 U.S.C. § 1320a-7(b)(6)(S);

e. not submit or cause to be submitted bills or requests for payment substantially in excess of the physician ' s usual charges for the same treatment or services, 42 U.S.C. § 1320a-7(b)(6)(A); 42 U.S.C. § 1001.101 (a)(2); HCFA Carrier Manual § 14006.1;

f. certify when presenting a claim that the service provided is a medical necessity, 42 U.S.C. § 1395n(a)(2)(8); and

g. comply with the Social Security Act ("SSA") and all regulations, Final Rules and other governmental directives and instructions.

149. Other sections of the statutes and regulations reiterate and affirm these obligations.

150. Under section 1862(a)(1)(A) of the SSA, items and services must be established as safe and effective to be considered medically necessary.

151. Medical devices that are not approved for marketing by the FDA are considered investigational and are not considered reasonable and medically necessary under SSA § 1862(a)(1)(A).

152. Medicare payment, therefore, may not be made for Coflex because it has not been approved for marketing by the FDA to be used for posterior non-segmental instrumentation (the definition of CPT 22840) and has not been deemed reasonable and medically necessary for that indication. The only indication Coflex has been approved for by the FDA is for interlaminar stabilization as a Class III Prosthesis, Spinous Process Spacer/Plate. The FDA assigned Coflex as a Class III device with a five-year expiration date because the safety and efficacy of Coflex has not yet been proven and fully supported. Taking safety and efficacy concerns into consideration, the vast majority of payors who have

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reviewed Coflex have deemed it experimental and investigational and have advised providers to bill for it using 0171T.

153. In deliberate contravention of these considerations, Paradigm and MCRA, in an effort to increase Coflex's usage and profitability, encouraged and instructed the sales representatives and distributors to promote Coflex under false billing codes to secure Medicare and other government reimbursements, for which Defendant is paid a portion by the performing provider, thereby promoting the device off-label.

154. The government payors would not have made payments to the hospitals and physicians for use of Coflex but for the fraudulent claims and submissions detailed herein. Specifically, the government payors would not have paid the providers for services that are not FDA approved, are still investigational and have not been deemed reasonable and medically necessary.

B. Coflex-F false and off-label marketing and promotion

155. Coflex-F received its 510K clearance on or about October 6, 2010 (#K093438). It is a Class II device that was given regulation number 888.3050, which refers to 21 CFR 888.3050, titled: "Spinal interlaminal fixation orthosis."

156. According to the 510K, Coflex-F was approved as follows:

> The Paradigm Interspinous Fusion Plate is a posterior, non-pedicle supplemental fixation device intended for use **with an interbody cage** as an **adjunct to fusion** at **a single level** in the **lumbar spine** (Ll – S1)**.** It is intended for attachment to the spinous processes for the purpose of achieving stabilization to promote fusion in patients with degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies - with **up to Grade I spondylolisthesis**.

(Emphasis supplied.) These intended uses stated in K093438 are the only ones approved by the FDA for the Coflex-F device.

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157. Paradigm and MCRA filed a supplement and received 510K clearance for slight a modification on or about February 13, 2012 (#K112595). This supplement **did not** change any intended uses, but only added "small- and medium-sized coflex-F Short devices to the coflex-F Implant System. The modifications are intended to allow the operating surgeon to better accommodate various patient anatomies. The modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device."

158. In summary, Coflex-F is not approved or intended to be used in more than one spinal level. It is not approved or intended to be used to treat severe spine conditions such as scoliosis or degenerative disc disease beyond the most minor, Grade I spondylolisthesis. It is also not intended to be used without fusion or an interbody.

159. On or about May 2011, Paradigm gave a training to its distributors across the United States, and later the same training was given at the National Training Meeting to distributors and employees. This training discusses Coflex (not yet approved) and Coflex-F.

160. This training gives distributors detailed talking and marketing points to use with physicians regarding Coflex, its advantages over competitors, etc., more than 18 months before it received Premarket Approval.

161. As for Coflex-F, one of the slides for this training discusses surgical technique and advises distributors to discuss multiple levels with surgeons. It advises to consider up to 5 levels. This slide spurred discussion internally on how to market Coflex-F for multi-level cases, when it is only approved for single level use.

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162. Paradigm trained its own employees and distributors to market and use Coflex-F for multiple spinal levels, contrary to FDA approval and indicated use.

163. For example, on June 16-17, 2012, in Loveland, Colorado, Paradigm had a "team training" led by Paradigm investor and high volume Coflex-F user, Dr. Pettine. All Paradigm Spine Managers, Clinical Personnel and Vice Presidents of Sales during that period attended this training. Dr. Pettine used Coflex-F sometimes with an interbody (as indicated) and sometimes not (off-label). He also has performed numerous multiple level Coflex-F cases. At this Paradigm training, Dr. Pettine shared his multi-level case experiences and even showed some slides demonstrating use without an interbody and multi-level use. This included showing x-rays from and touting a case Dr. Pettine had done using 3 contiguous Coflex-F devices, without rivets or an interbody. This x-ray and case study was also sent via text message to area managers for dissemination. The dissemination of these cases and use to educate physicians was off-label marketing and promotion.

164. In 2012, Dr. Pettine was on Paradigm's "Top Ten Surgeons" list as number one, with 171 cases (79 DSS and 92 Coflex-F).

165. On occasion, Paradigm management would distribute case studies, including x-ray films, demonstrating Coflex-F use off-label to spur its sales force to push the use of multiple levels in order to drive up company revenue. For example, an x-ray and short synopsis was emailed to all Paradigm Area Managers in 2012 for their dissemination internally and externally, which occurred. It showed Dr. Thalgott's surgery on patient N.J.W. at Valley Hospital Las Vegas on February 8, 2012. He used Coflex-F in a **4-level** construct. (Coflex-F is only indicated for single-level use). Dr. Thalgott has been a paid surgeon consultant and trainer for Paradigm Spine for Coflex-F.

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166. After being trained by Paradigm's distributor, Axis, on the multi-level use of Coflex-F, Dr. Clemente performed a multi-level case at Mountain Side Hospital in New Jersey on December 29, 2011 on male Medicare patient D.N. (dob: 7/11/39). He used Coflex-F size 8 on two levels at L3-L4 and L4-L5, for a total of $15,800 charged for the devices. Dr. Clemente was paid.

167. After having been trained by Paradigm on multi-level use of Coflex-F, Dr. Dannis operated on female Medicare patient G.V. (dob: 9/7/43) at Mountain Side hospital on March 22, 2013. He used a two-level Coflex-F construct at levels L2-L3 and L3-L4 and was paid.

168. After having been trained by Paradigm on multi-level use of Coflex-F, Dr. Clemente operated on a male Medicare patient D.R. (dob: 2/22/38) at Clara Maass Medical Center in Belleville, New Jersey on February 15, 2013. He used a two-level Coflex-F construct (sizes 10mm and 12mm) for a total of $17,000 and was paid.

169. According to Paradigm's internal Coflex-F case tracker, 40% of the cases in 2011 were more than one level (off-label) and more than 30% of the cases in 2012 were more than one level (off-label).

170. Paradigm's distributors were not only trained and educated to market Coflex-F for non-approved uses, but were compensated by Paradigm for off-label marketing and use by their physicians. Paradigm kept careful track of off-label and on-label cases and paid its distributors for both.

171. Paradigm trains its sales force and distributors to promote, market and sell Coflex-F to physicians to be used in more than a single level. Sales staff and distributors are

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trained to, and routinely do, falsely market and promote DSS for two, three, four and five spinal levels. This constitutes off-label marketing.

172. Paradigm regularly and continuously conducts physician trainings, including practice on cadavers in labs, demonstrating how to use Coflex-F devices in two, three, four and five contiguous spinal levels. This training and promotion constitutes false and off-label marketing.

173. For Coflex-F, Paradigm also paid fees to surgeons to complete intra-operative and post-operative Paradigm surveys titled Product Evaluation Forms. A flat fee of $500 was paid to each surgeon who competed and returned the two short surveys. This program was in effect in 2011 but soon thereafter was suspended after the issue of improper inducements was voiced by distributors. Of the surgeons who participated in and were paid to fill out a short four-page survey about Coflex-F, the vast majority were still using Coflex-F in 2012, including Drs. Peloza, Salib, Bergey, Nathan, Dryer, Demakas, Lopez, White and Barry.

C. DSS false and off-label marketing and promotion

174. The DSS Stabilization System- Rigid Coupler (common name: pedicle screw spinal system) received its 510K clearance on or about November 28, 2008 (#K080241). It is a Class II device under regulation 21 CFR § 888.3070.

175. According to the 510K, the DSS device is intended only for single-level use as follows:

> The DSS Stabilization System- Rigid is intended as a **single-level** system for noncervical pedicle fixation from the T4 to S1 vertebrae in skeletally mature patients to help provide immobilization and stabilization of spinal segments as an **adjunct to fusion** for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion. The

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> DSSTM Stabilization System- Rigid is intended to be used with autograft and/or allograft.

(Emphasis supplied).

176. On or about June 19, 2009, Paradigm supplemented its DSS filing and received additional 510K clearance for DSS (# 090099). In this 510K, DSS is classified as a Class III device. This 510K added the DSS Stabilization System–Slotted as an additional variation. While the intended use for the Rigid remained unchanged, the intended use of the Slotted differs and is as follows:

> DSS™ Stabilization System–Slotted
>
> The DSS™ Stabilization System–Slotted is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, kyphosis, and failed previous fusion (pseudarthrosis).
>
> In addition, the DSS™ Stabilization System –Slotted is indicated for use in patients:
> - Who are receiving fusions with autogenous graft only;
> - Who are having the device fixed or attached to the lumbar or sacral spine;
> - Who are having the device removed after the development of a solid fusion mass.

177. Critically, the 510K clearly states, "**Note: The Rigid Coupler and Slotted Coupler are not intended to be used together.**"

178. Three more DSS 510K clearances were issued: (a) on July 2, 2010 (#K101083); (b) on January 10, 2010 (#K113625); and (c) on May 9, 2012 (#K 120491). For all relevant purposes herein, there was no change in the intended uses. #K113625 simply modified by adding a straight rod to the DSS system and #K120491 clarified that the straight rods are for multi-level use, while the Rigid itself remains for single-level use.

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179. These 510Ks continued to ban the use of the Rigid and Slotted together, all containing the following: "**Note: The Rigid Coupler and Slotted Coupler are not intended to be used together**."

180. Despite the multiple DSS 510Ks, all stating that the Rigid and Slotted are not to be used together, in reality, there was no way in 2008-2010 and into 2011 to attach the Slotted DSS coupler to a fusion without the Rigid coupler. As such, close to all DSS use in 2008, 2009, 2010 and 2011 was done using the Rigid and the Slotted together and not as intended or approved.

181. Paradigm knew this reality, and never advised, trained or otherwise informed the surgeons of this conflict with the approved use and also never advised the FDA. Paradigm intentionally omitted this information from surgeons and the FDA in an effort to keep DSS sales and revenue up and not to lose this stream of business.

182. On April 7, 2011, Paradigm's VP of Sales, Matt Stuttle, emailed the field an example of DSS being used off-label (Rigid and Slotted together). It was emailed as an example of the DSS possibilities and was meant to be disseminated internally and externally, which occurred. The example shows an x-ray from Dr. Peter Witt's April 2011 DSS surgery at the hospital at the University of Colorado. Instead of advising that the use shown in his email was off-label, Stuttle encouraged the same, writing "anything is possible…DSS… Start selling!"

183. Similarly, on July 30, 2011, Paradigm's DSS National Manager, John Maynard, emailed a group of Paradigm managers a recent DSS surgery for their education and for their use, reference, training purposes and dissemination both internally and externally. This email touted a recent surgery by Dr. Dietze in New Orleans on July 26, 2011

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on patient R.G. using the DSS rigid and slotted together and off-label. Maynard distributed the fleuro images from the surgery as an email movie clip so other surgeons could actually see the off-label use of DSS in a real surgery. Far from advising that this use was off-label, Maynard proclaimed that this is a "great example of DSS in action."

184. On August 26, 2011, Paradigm's VP of Marketing, Dominik Beck, emailed a group of Paradigm managers for distribution to all employees and distributors. This email touted a recent three-level DSS case in Germany and included fleuro images of the case. This off-label case was sent to the managers for distribution to all distributors in the same email in which Paradigm announced a sales incentive in which distributors would get $250 per case for the first five cases done by new surgeons. Highlighting that the more level's the better, in the three-level off-label sample case, the VP of Marketing noted in his email to "Take a look at the Fleuro-Screen. That is 25 Grand right here."

185. Given the Paradigm training and extreme incentives to distributors to encourage multi-level use, DSS was used in multi-level cases 56.2% of the time in 2012 according to Paradigm's statistics. This included seven five-level cases and one seven-level case.

186. Paradigm hosted and paid for a weekend retreat for DSS surgeons. It was referred to as a "Think Tank at the Farm of Dr. Art Steffee." Dr. Steffee was not independent from Paradigm; in fact, he was a Director. It was held on October 21-22, 2011 and was attended almost exclusively by surgeons who were DSS users. Attendees included Drs. Bailey, Wolf, Donner, Piper, Salib, Kennedy and Robinson. The weekend started with cocktails and dinner at Dr. Steffee's house for the surgeons and members of Paradigm's education team. Saturday, October 22, 2011 started with breakfast paid for by Paradigm

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followed by a DSS presentation by Dr. Art Steffee in which, upon information and belief, he touted its off-label use, including multi-level use and the use of the Rigid and Slotted together. After the presentation and discussion, surgeons were treated to lunch at the Allegheny Grille and then an afternoon of golf at Foxburg Country Club or wine tasting at Foxburg Winery. In 2012, Drs. Salib, Donner and Bailey all made Paradigm's "Top Ten Surgeons" list for their DSS and Coflex-F use.

187. Paradigm trains its sales force and distributors to promote, market and sell DSS to physicians to be used in more than a single level and to use the Rigid and Slotted together. Sales staff and distributors are trained to, and routinely do, falsely market and promote DSS for three, four and five spinal levels. This constitutes off-label marketing.

188. After being trained on DSS multi-level use and attending the Steffee Farm meeting and presentation, on November 2, 2012 at S1 Spine, LLC in Pennsylvania, Dr. Wolf operated on patient R.A.H. using a three-level DSS construct for a total of $20,320 and he was paid for this off-label surgery as was the Paradigm distributor, S1Spine, who received commission for the multi-level case.

189. After being trained on DSS multi-level use, on October 15, 2012 at Methodist Hospital in Texas, Dr. Johnson operated on patient V.E. using a three-level DSS construct for a total of $20,845 and he was paid for this off-label surgery as was the Paradigm distributor, Rob Donahue, who received commission for the multi-level case. On September 28, 2012 at Methodist Hospital in Texas, Dr. Johnson operated on patient P.K.R. using a four-level DSS construct for a total of $26,320 and he was paid for this off-label surgery as was the Paradigm distributor, Rob Donahue, who received commission for the multi-level case.

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190. After being trained on DSS multi-level use and being a Paradigm investor, on September 5, 2012 at Poudre Valley Hospital in Colorado, Dr. Pettine operated on patient E.S. using a three-level DSS construct for a total of $18,000 and he was paid for this off-label surgery as was the Paradigm distributor, Rocky Mountain Surgical, who received commission for the multi-level case. On September 10, 2012 at Poudre Valley Hospital in Colorado, Dr. Pettine operated patient E.L. using a two-level DSS construct for a total of $13,800 and he was paid for this off-label surgery as was the Paradigm distributor, Rocky Mountain Surgical, who received commission for the multi-level case. On September 12, 2012 at Poudre Valley Hospital in Colorado, Dr. Pettine operated patient M.L.C. using a two-level DSS construct for a total of $12,300 and he was paid for this off-label surgery as was the Paradigm distributor, Rocky Mountain Surgical, who received commission for the multi-level case. On September 17, 2012 at Poudre Valley Hospital in Colorado, Dr. Pettine operated on patient A.A.A. using a two-level DSS construct for a total of $12,300 and he was paid for this off-label surgery as was the Paradigm distributor, Rocky Mountain Surgical, who received commission for the multi-level case. On September 24 2012 at Poudre Valley Hospital in Colorado, Dr. Pettine operated patient M.J.W. using a two-level DSS construct for a total of $11,100 and he was paid for this off-label surgery as was the Paradigm distributor, Rocky Mountain Surgical, who received commission for the multi-level case.

191. After being trained on DSS multi-level use, on July 19, 2012 at Baptist Hospital in Tennessee, Dr. Law operated on patient L.E.A. using a two-level DSS construct for a total of $11,800 and he was paid for this off-label surgery as was the Paradigm distributor, Z-Med, Inc., who received commission for the multi-level case. On July 20, 2012 at Centennial Medical Center in Tennessee, Dr. Law operated on patient D.K.G. using a three-

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level DSS construct for a total of $12,450 and he was paid for this off-label surgery as was the Paradigm distributor, Z-Med, Inc., who received commission for the multi-level case. On July 23, 2012 at Centennial Medical Center in Tennessee, Dr. Law operated on patient D.N.R. using a three-level DSS construct for a total of $15,160 and he was paid for this off-label surgery as was the Paradigm distributor, Z-Med, Inc., who received commission for the multi-level case.

192. On information and belief, a portion of these off-label DSS cases were performed on Medicare patients and were paid for by government payors.

D. Physician Owned Distributor

193. Paradigm is a privately held entity that derives revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician investors for use in procedures the physician investors perform on their own patients. An entity like this is generally referred to as a Physician Owned Distributor or "POD." As the Office of Inspector General has warned, "given the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers, we believe these ventures should be closely scrutinized under the fraud and abuse laws." Letter from Vicki Robinson, Chief, Industry Guidance Branch, Department of Health and Human Services, OIG, Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries (Oct. 6, 2006).

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194. In addition to various non-physician owners, Paradigm has owners and dozens of investors, officers and directors who are spine surgeons. Other spine surgeons are investors in Viscogliosi Brothers, LLC, which is a beneficial owner of and controls Paradigm.

195. These spine surgeon investors were selected to invest in Paradigm specifically because of their medical specialties in the spine field. These spine surgeon investors are in a special position to generate business for Paradigm by using and referring the use of Paradigm's spinal devices. In fact, the only physicians who are investors in Paradigm are spine surgeons or in the spine field.

196. Moreover, of Paradigm's list of Top Ten Surgeons for 2012 (those with the most Paradigm cases for the year), four of the ten are also Paradigm investors, including Drs. Pettine (#1), Thalgott (#2), Donner (#5) and Davis (#10). Dr. Pettine had 171 cases in 2012 using Paradigm devices. Dr. Thalgott had 98 cases in 2012 using Paradigm devices. Dr. Donner had 40 cases in 2012 using Paradigm devices. Dr. Davis had 28 cases in 2012 using Paradigm devices.

197. Another Paradigm spine surgeon investor, Dr. Gornette, is a user of Coflex and Coflex-F through an ambulatory surgical center (ASC) that he owns.

198. As investors in Paradigm, the physicians have incentives not only to use Paradigm's devices over other (competitors') devices, but, these spine surgeon investors have used Paradigm's devices off-label as described above and have used Paradigm's signature device, Coflex, and been improperly paid by billing CPT 22840.

199. In addition, Paradigm included numerous spine surgeon investors in its PMA clinical investigations for Coflex. Its PMA requires an investigational device exemption study

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(IDE) of Coflex. Paradigm used physician investors for this study, including Drs. Davis, Pettine, Bae and Spivak.

200. As for Dr. Davis, a spine surgeon investor who had been a lead Coflex investigator and chief author on the PMA study, shortly before Paradigm went before the FDA for final approval for Coflex, Dr. Davis was bought out of his shares so as not raise too much suspicion about the study or about Paradigm's investor make-up.

CLAIMS

COUNT 1
FALSE CLAIMS ACT VIOLATION
(Violation of 31 U.S.C. § 3729(a)(1)(A) – **UPCODING TO 22840**
Against Defendants Paradigm and MCRA)

201. Relator realleges, adopts and incorporates by reference all allegations in the Complaint as if specifically reiterated herein.

202. Paradigm has sales representatives and distributors covering more than 50% of the country. By virtue of the kickbacks, select investor opportunities, misrepresentations and submissions of non-reimbursable claims described above, in at least 32 states, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment to the United States Government and state governments through state health insurance programs and Defendants continue to do so through today. Defendants intended that their false statements be used to get the Government to pay the false claims to hospitals and physicians.

203. Coverage under Medicare is limited to medical services that are "reasonable and necessary" for the diagnosis or treatment of illness or injury. *See* 42 U.S.C. § 1395y(a)(1)(A) (defining scope of Medicare benefits). Although a physician may lawfully use a device off label if it independently chooses to do so based on his or her opinion and the best interest of the patient, there is no mandate that Medicare cover services involving such off-

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label uses. However, to the extent that a healthcare provider seeks reimbursement for a procedure that is ineligible for payment under a federal healthcare program, either because the program bars coverage for a particular off-label use of a device or because the program places other conditions on coverage that are not satisfied, and the off-label use was a result of false marketing and promotion from the device manufacturer or seller, the resulting claim is false. Paradigm and MCRA knowingly and intentionally caused hospitals and physicians to submit such false claims for Coflex as described herein.

204. By training, coaching and encouraging hospitals and physicians to bill Coflex under wrong and deceptive billing codes, Defendants caused hospitals and physicians to secure reimbursement for medical services that were not reasonable and medically necessary. Thus, Defendants knowingly caused to be presented false or fraudulent claims for payment to the Medicare and various state programs.

205. Additionally, by training, coaching and encouraging hospitals and physicians to bill Coflex under wrong and deceptive billing codes, and in an effort to increase the usage and profitability of its signature device, Coflex, Defendants successfully encouraged and coached hospitals and physicians to submit false codes to Medicare and state health plans to obtain fraudulent reimbursement, and reimbursement that would not otherwise had been paid if CPT 22840 had not been used. As a result of training from Paradigm and MCRA, hospitals and physicians billed Defendant's Coflex under CPT 22840 when it has not been approved as "Posterior non-segmental instrumentation" or given any Category 1 CPT code of its own, thereby defrauding Government payors.

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206. Moreover, by coaching hospitals and physicians to bill Coflex under wrong billing codes, Defendants caused false claims to be presented to federal and state government payors and wrongfully reimbursed by state and the federal governments.

207. Defendants also deliberately instructed and advised hospitals and physicians, through the off-label promotion of Coflex, to submit bills for Coflex under false billing codes (22840) in order to obtain reimbursement for spine surgeries performed at various Veterans Administration hospitals and, upon information and belief, reimbursed under the federal military healthcare plan known as TRICARE. As a result, TRICARE was defrauded and paid providers for Coflex services that would not have been reimbursed if coded correctly.

208. As demonstrated through direct instruction by Dr. Mathews in presentations, Web-x seminars and labs, and numerous sales and informational meetings, Defendants knowingly caused to be presented to federal and state government payors fraudulent claims in order to help hospitals and physicians obtain improper reimbursement for Coflex so as to increase Coflex's use, appeal in the marketplace and profitability.

209. Defendant knew that Coflex was not approved specifically by the FDA as a "posterior non-segmental instrumentation," that it had no independent guidance to use CPT 28840, and that the only guidance it had received was that Coflex is experimental and investigational and should be coded using the T-code or possibly the unlisted code, both of which trigger heightened scrutiny, review and usually claim rejection or limitation. Instead, Defendants knowingly trained, coached and encouraged its sales representatives and distributors to omit that guidance when marketing Coflex, and instead to encourage the use of CPT 22840 to physicians and DRG 490 and 491 to hospitals.

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210. Thus, Defendants knowingly caused the Medicare program and state health insurance programs to be charged and presented payment for services that were not reasonable and medically necessary for services that were not approved by the FDA, for a device that is experimental and investigational, and that was not reimbursable under Medicare and state health insurance programs.

211. The federal Medicare program and various state programs made payments to Paradigm's physician and hospital clients based upon false and fraudulent claims and thereby suffered damages. The United States Government and the state programs are entitled to full recovery of the amount paid by them for the false or fraudulent claims.

212. As set forth in the preceding paragraphs, Defendants knowingly violated 31 U.S.C. § 3729(a)(1)(A) and have damaged the United States by their actions in an amount to be determined at trial.

COUNT 2
FALSE CLAIMS ACT VIOLATION
(Violation of 31 U.S.C. § 3729(a)(1)(B) - **UPCODING TO 22840**
Against Defendants Paradigm and MCRA)

211. Relator realleges, adopts and incorporates by reference all allegations in the Complaint as if specifically reiterated herein.

212. By virtue of the kickbacks, select investor opportunities, misrepresentations and submissions of non-reimbursable claims described above, throughout the states serviced by Paradigm, including Texas, Arkansas, Arizona, Pennsylvania, New Jersey, New York, Ohio, California, Georgia, Kentucky, Indiana, Montana, Tennessee, Maryland, Illinois,

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Mississippi, Florida, South Dakota, Oregon, Washington, Alabama, Nevada, Minnesota, North Carolina and Wyoming, Defendants knowingly caused to be made or used, false records or statements material to a false or fraudulent claims to the United States Government and state payors. Defendants continue to do so. Defendants intended that their false marketing and promotion would cause false statements be used or submitted to get the federal and state governments to pay the false claims to hospitals and physicians.

213. Defendants knowingly caused the Medicare and state programs to be charged and presented payment for services that were not reasonable and medically necessary, that were experimental and investigational, and for services that were not Medicare compliant.

214. Defendants knowingly caused to be presented false or fraudulent claims for payment to the Medicare and state programs by falsely promoting Coflex off-label using an improper and false Category 1 CPT code in order to ensure coverage of this device, which would not otherwise be covered.

215. As a result of Defendants' fraudulent course of conduct, Defendants caused to be made or used, a false record or statement material to a false or fraudulent claim to the Government for the Medicare program and to the states for their state Medicare and Medicaid programs. These claims were not reimbursable because the FDA did not approve Coflex for posterior non-segmental instrumentation (22840) and because posterior non-segmental instrumentation and Code 22840 connotes and indicates a surgery that is more complex and requires more technical know-how, more time, the use of rods, screws or wiring and greater associated patient risk than does the surgery using Coflex.

216. The federal Government, through its proxies under the Medicare program, and state governments made payments to Defendant's physician and hospital clients based upon

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false and fraudulent claims and thereby suffered damages. The federal and state governments are entitled to full recovery of the amount they paid for these false or fraudulent claims.

217. As set forth in the preceding paragraphs, Defendants knowingly violated 31 U.S.C. § 3729(a)(1)(B) and have damaged the United States and various states named herein by their actions in an amount to be determined at trial.

COUNT 3
FALSE CLAIMS ACT VIOLATION
(Violation of 31 U.S.C. § 3729(a)(1)(A) – **OFF-LABEL COFLEX-F and DSS**
Against Defendant Paradigm)

218. Relator realleges, adopts and incorporates by reference all allegations in the Complaint as if specifically reiterated herein.

219. Paradigm has sales representatives and distributors covering more than 50% of the country. By virtue of the kickbacks, select investor opportunities, misrepresentations and submissions of non-reimbursable claims described above, in at least 32 states, Defendant knowingly presented or caused to be presented false or fraudulent claims for payment to the United States Government and state governments through state health insurance programs and Defendant continues to do so through today. Defendant intended that its false statements be used to get the Government to pay the false claims to hospitals and physicians.

220. Coverage under Medicare is limited to medical services that are "reasonable and necessary" for the diagnosis or treatment of illness or injury. *See* 42 U.S.C. § 1395y(a)(1)(A) (defining scope of Medicare benefits). Although a physician may lawfully use a device off label if it independently chooses to do so based on his or her opinion and the best interest of the patient, there is no mandate that Medicare cover services involving such off-label uses. However, to the extent that a healthcare provider seeks reimbursement for a procedure that is ineligible for payment under a federal healthcare program, either because the

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program bars coverage for a particular off-label use of a device or because the program places other conditions on coverage that are not satisfied, and the off-label use was a result of false and misleading marketing and promotion from the device manufacturer or seller, the resulting claim is false. Paradigm knowingly and intentionally caused hospitals and physicians to submit such false claims for Coflex-F and DSS as described herein.

221. By training, coaching and encouraging hospitals and physicians to use Coflex-F and DSS for multi-level spinal use and to use the DSS Rigid and Slotted couplers together, Defendant caused hospitals and physicians to secure reimbursement for medical services that were off-label and were not reasonable and medically necessary. Thus, Defendant knowingly caused to be presented false or fraudulent claims for payment to the Medicare and various state programs.

222. Additionally, by training, coaching and encouraging hospitals and physicians to use Coflex-F and DSS for multiple levels and to use DSS Rigid and Slotted together, and in an effort to increase the usage and profitability of these devices, Defendant successfully encouraged and coached hospitals and physicians to use these devices for more than the intended and approved uses to obtain fraudulent reimbursement, and reimbursement that would not otherwise had been paid if the Defendant had not pushed this aggressive, false and misleading marketing scheme.

223. Moreover, by advancing this false and misleading off-label marketing and promotion, Defendant caused false claims to be presented to federal and state government payors and be wrongfully reimbursed by state and the federal governments.

224. As off-label uses were demonstrated, trained and encouraged through Paradigm's distributors and at lab trainings and dinner presentation and paid physician

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weekend getaways (like at DR. Steffee's farm), Defendant knowingly caused to be presented to federal and state government fraudulent claims in order to help hospitals and physicians obtain improper reimbursement for Coflex-F and DSS so as to increase these devices' use, appeal in the marketplace and profitability.

225. Defendant knew that Coflex-F and DSS were not approved for multiple level use and knew that using the DSS Rigid and Slotted couplers together was expressly prohibited. Instead, Defendant knowingly trained, coached and encouraged its sales representatives and distributors to conduct false and misleading marketing and promotion of these devices to encourage off-label use.

226. Thus, Defendant knowingly caused the Medicare program and state health insurance programs to be charged and presented payment for services that were not reasonable and medically necessary, were not approved, were off-label, and that were therefore not reimbursable under Medicare and state health insurance programs.

227. The federal Medicare program and various state programs made payments to Paradigm's physician and hospital clients based upon false and fraudulent claims and thereby suffered damages. The United States Government and the state programs are entitled to full recovery of the amount paid by them for the false or fraudulent claims.

228. As set forth in the preceding paragraphs, Defendant knowingly violated 31 U.S.C. § 3729(a)(1)(A) and have damaged the United States by their actions in an amount to be determined at trial.

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COUNT 4
FALSE CLAIMS ACT VIOLATION
(Violation of 31 U.S.C. § 3729(a)(1)(B) – **OFF-LABEL COFLEX-F and DSS** Against Defendant Paradigm)

229. Relator realleges, adopts and incorporates by reference all allegations in the Complaint as if specifically reiterated herein.

230. By virtue of the kickbacks, select investor opportunities, misrepresentations and submissions of non-reimbursable claims described above, throughout the states serviced by Paradigm, Defendant knowingly caused to be made or used, false records or statements material to a false or fraudulent claims to the United States Government and state payors. Defendant continues to do so. Defendant intended that its false marketing and promotion would cause false statements be used or submitted to get the federal and state governments to pay the false claims to hospitals and physicians.

231. Defendant knowingly caused the Medicare and state programs to be charged and presented payment for services that were not reasonable and medically necessary, that were off-label, and for services that were not Medicare compliant.

232. Defendant knowingly caused to be presented false or fraudulent claims for payment to the Medicare and state programs by engaging in false and misleading marketing and promotion surrounding Coflex-F and DSS in order to increase sales and revenue.

233. As a result of Defendant's fraudulent course of conduct, Defendant caused to be made or used, a false record or statement material to a false or fraudulent claim to the Government for the Medicare program and to the states for their state Medicare and Medicaid programs. These claims were not reimbursable because the FDA did not approve Coflex-F and DSS for multiple level use or for the DSS Rigid and Slotted to be used together.

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234. The federal Government, through its proxies under the Medicare program, and state governments made payments to Defendant's physician and hospital clients based upon false and fraudulent claims and thereby suffered damages. The federal and state governments are entitled to full recovery of the amount they paid for these false or fraudulent claims.

235. As set forth in the preceding paragraphs, Defendants knowingly violated 31 U.S.C. § 3729(a)(1)(B) and have damaged the United States and various states named herein by their actions in an amount to be determined at trial.

COUNT 5
FALSE CLAIMS ACT VIOLATION
(Violation of 31 U.S.C. § 3729(a)(1)(C) – **Conspiracy**
Against Defendants Paradigm and MCRA)

236. Relator realleges, adopts and incorporates by reference all allegations in the Complaint as if fully reiterated herein.

237. By training, coaching and encouraging hospitals and physicians to bill Coflex under wrong and deceptive billing codes, Defendants caused hospitals and physicians to secure reimbursement for medical services that were not reasonable and medically necessary. Thus, Defendants knowingly caused to be presented false or fraudulent claims for payment to the Medicare and various state programs.

238. Additionally, by training, coaching and encouraging hospitals and physicians to bill Coflex under wrong and deceptive billing codes, and in an effort to increase the usage and profitability of its signature device, Coflex, Defendants successfully encouraged and coached hospitals and physicians to submit false codes to Medicare and state health plans to obtain fraudulent reimbursement, and reimbursement that would not otherwise had been paid if CPT 22840 had not been used. As a result of training from Paradigm and MCRA, hospitals and physicians billed Defendant's Coflex under CPT 22840 when it has not been approved as

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"Posterior non-segmental instrumentation" or given any Category 1 CPT code of its own, thereby defrauding Government payors.

239. Moreover, by coaching hospitals and physicians to bill Coflex under wrong billing codes, Defendants caused false claims to be presented to federal and state government payors and wrongfully reimbursed by state and the federal governments.

240. Defendants Paradigm and MCRA entered into an unlawful agreement to cause false or fraudulent claims to be paid by the Government, they shared in this general conspiratorial objective, and they took overt acts in furtherance of this unlawful agreement as detailed herein.

241. Thus, Defendants conspired to and knowingly caused the Medicare program and state health insurance programs to be charged and presented payment for services that were not reasonable and medically necessary for services that were not approved by the FDA, for a device that is experimental and investigational, and that was not reimbursable under Medicare and state health insurance programs.

242. As a result of Defendants' conspiracy, the federal Medicare program and various state programs made payments to Paradigm's physician and hospital clients based upon false and fraudulent claims and thereby suffered damages. The United States Government and the state programs are entitled to full recovery of the amount paid by them for the false or fraudulent claims.

243. As set forth in the preceding paragraphs, Defendants knowingly violated 31 U.S.C. § 3729(a)(1)(C) and have damaged the United States by their actions in an amount to be determined at trial.

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COUNT 6
FALSE CLAIMS ACTI VIOLATION - FEDERAL ANTI-KICKBACK STATUTE

(Violation of 31 U.S.C. §3729(a)(1)(C) – Against Defendant Paradigm)

244. Relator realleges, adopts and incorporates by reference all allegations in the Complaint as if fully reiterated herein.

245. The Anti-Kickback Statute, 42 U.S.C. §1320a-7b, prohibits any person from knowingly and willfully offering or paying any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to any person to induce such person to purchase, order, arrange for, or recommend purchasing or ordering any good, service, or item for which payment may be made (in whole or in part) under a federal health care program.

246. Through meals, entertainment, lodging, golf and wine tastings, Paradigm has knowingly and willfully offered and paid remuneration directly to physicians to induce those physicians to purchase, order, or arrange for the purchasing or ordering of Coflex, DSS and Coflex-F devices, where payment would be made (in whole or in part) under a federal or state health care program.

247. Through offering investor opportunities solely to spine surgeons, Paradigm has knowingly and willfully offered and paid remuneration directly to physicians to encourage and induce those physicians to purchase, order, use or arrange for the purchasing or ordering of Coflex, DSS and Coflex-F devices, where payment would be made (in whole or in part) under a federal or state health care program.

248. Paradigm knew that each Medicare and Medicaid provider is required to enter into a provider agreement with the Government (CMS Form 855 A, 855B, or 8551) and that under the terms of that agreement, each Medicare or Medicaid provider certifies that it will

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comply with all laws and regulations concerning proper practices for those providers. One of the laws included in this certification is the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(B).

249. A Medicare or Medicaid provider's compliance with the provider agreement is a condition for receipt of payments under the Medicare or Medicaid program.

250. Physicians who receive payments in violation of the Anti-Kickback Statute violate their certifications and are disqualified from receiving payment as part of the Medicare or Medicaid programs.

251. As a result of Paradigm's payments to physicians in violation of the Anti-Kickback Statute, and their receipt of those payments, the physicians became ineligible to receive payment under the Medicare or Medicaid programs.

252. Moreover, payments to the select spine surgeon investors in Paradigm, for who there is an inherent opportunity for them to earn a profit as an investor for using Paradigm devices, constitutes illegal remuneration under the anti-kickback statute. These spine surgeon investors were selected for the investment opportunity because they are in a position to generate substantial business for Paradigm, and they have done so. This is a corruption of their medical judgment, results in a decrease in the regular and fair competition in the medical device industry, leads to overutilization of the device, in this instance has resulted in increase of off-label use and upcoding, and yields an overall increased cost to the Federal and state health care programs and beneficiaries.

253. Paradigm knew and intended that providers who were ineligible under the Medicare and Medicaid programs (as a result of Paradigm's payments to them, and their receipt of those payments in violation of the Anti-Kickback Statute) would submit claims for payment to the Medicare and Medicaid programs for the purchase and use of Paradigm's

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devices: DSS, Coflex and Coflex-F. These claims by physicians were false, and Paradigm caused their submission.

254. As set forth in the preceding paragraphs, Paradigm conspired with private physicians, other health care providers and other third-party interests (including MCRA) who assisted Defendant in its illegal off-label marketing campaign to defraud the United States and the various states by getting false and/or fraudulent Medicare and Medicaid claims paid for Paradigm devices in violation of 31 U.S.C. § 3729(a)(1)(C).

255. Paradigm, by and through its officers, agents and employees, authorized and encouraged its various officers agents, and employees to take the actions set forth above.

256. As a result of Paradigm's acts, the United States Government and various states reimbursed physicians for medical devices that it otherwise would not have if Paradigm had not presented false and misleading information to the physicians in an effort to promote *off-label* and medically unnecessary use of Coflex, DSS and Coflex-F.

257. Each medical device that was used as a result of Defendant's false and illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. Each claim for reimbursement for such off-label or illegally-induced use of the medical device submitted to a federal or state health insurance program represents a false or fraudulent claim for payment.

258. By reason of Paradigm's acts, the United States and the various states named herein have been damaged, and continue to be damaged, in a substantial amount to be determined at trial. Federal and state health insurance programs have paid numerous claims for off-label medical devices for indications that were not approved by the FDA, were not reasonable and necessary to treat patients, not medically necessary, and/or otherwise induced

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and caused by Paradigm's massive fraud, off-label marketing and kickback payments. The use and purchase of these medical devices and the corresponding claims to federally-funded and state-funded health care programs were a foreseeable and intended result of Paradigm's illegal acts.

PRAYER FOR RELIEF

WHEREFORE, Relator prays, on behalf of the United States and himself, that on final trial of this case, judgment be entered in favor the United States and against Defendants as follows:

A. That as to all Counts, judgment be entered for the United States Government and against the Defendants for the maximum amount of the United States' damages, multiplied as required by law and for such civil penalties as are allowed by law, including, but not limited to, statutory penalties for each violation, treble damages, attorneys' fees and costs; and

B. For the costs of this action, prejudgment interest, interest on the judgment, attorneys' fees and for any other and further relief to which the United States and the Relator may be justly entitled.

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JURY DEMAND

Relator hereby demands a jury trial as to all issues so triable.

Jay P. Holland

Respectfully submitted,

JOSEPH, GREENWALD & LAAKE, P.A.

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